Introducing the Innovative Health Initiative - IHI
Outline

- Why an IHI JU?
- Governance, SRIA, Objectives
- Applying for funding
- Indicative topics for the first calls
- How to get involved
- Keep up to date
Why a new partnership?

- COVID-19 has demonstrated that the public and private sectors must work together to address the immediate public health challenges.
- Challenges around the uptake of innovations in healthcare.
- Increasing burden of disease for patients; increasing costs of healthcare delivery.
- Address the main finding of IMI2 interim evaluation: “enable the active engagement of other industry sectors with the pharmaceutical industry to capitalise on their expertise in the development of new health care interventions”.

- A new partnership should have a broader scope/wider range of stakeholders:
  - Integrating various technologies (pharmaceutical, medtech, biotech, imaging, vaccines) for better prevention, diagnosis and treatment;
  - Better responding to public health needs;
  - Better addressing the requirements of patients and health care professionals;
  - More openness to new ideas from external stakeholders.

- Cross-sectoral collaboration should be at the heart of a future health PPP.
Moving to a new EU/Industry partnership in healthcare

Need for change

- Siloed industries
- Different sets of standards
- Translation of science
- Reimbursement focus
- Locked value of data analytics

Rapid advances

- Scientific and tech advancements
- Digital therapies appearing
- Precision therapies and personalised medicines emerging
- Big data as a critical enabler

New cross-sector PPP

- Diagnostics and biotech to bring new capabilities and standards
- Cross-sector activities will aim to remove siloed activity
- Support translation of scientific and tech advances while harnessing big data to improve health

Credits: COCIR, EFPIA, EuropaBio, MedTech Europe,
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
- Vaccines Europe

The public member in the partnership is the European Union, represented by the European Commission.
A new Strategic Research and Innovation Agenda

The Science and Innovation Panel

One and two stage calls

- 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.
IHI JU Budget

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 contributes to EU policies

IHI’s projects are expected to contribute to EU policies:

- 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 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.
Governance
GOVERNING BOARD

EU, represented by European Commission

COCIR

Europa Bio

EFPIA incl. Vaccines Europe

MedTech Europe

States Representatives Group

Science & Innovation Panel

Executive Director

IHI Office

Contributing partners

Source: Council Regulation - Single Basic Act
Role of the SIP

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

- 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

- **2 members** European Commission
- **4 members** IHI industry partners
- **2 members** States Representatives Group (SRG)
- **Chair**
- **4 members** Scientific community
- (up to) **6 members** Stakeholders involved in healthcare (e.g. patients, health care professionals, healthcare providers, regulatory bodies, HTA, payers...)

Representatives appointed by own body

Representatives appointed via EoI Call

*ad-hoc panelists* may be invited to discuss specific subjects at given meetings
SIP Permanent Members

Scientific Community
- Mario Campone
- Anna Chioti
- Jiri Mekyska
- Maroeska Rovers

Stakeholders
- Katariina Gehrmann (HC providers)
- Ralf Herold (regulators)
- Eva Hummers (HC professionals)
- Peter Kapitein (patients)
- Annika Tibell (HC prof/providers)
- Claudia Wild (HTA bodies)

IHI founding members
- Sibilia Quilici (EuropaBio & Vaccines Europe)
- Bernd Stowasser (EFPIA)
- Ceri Thompson (EC)
- Arjon van Hengel (EC)
- Nathalie Virag (Medtech Europe)
- Joanna Wills (COCIR)

IHI States’ Representatives Group
- Martha Cahill (IE)
- Jan Skriwanek (DE)
Strategic Research and Innovation Agenda (SRIA)
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.
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**.
Specific objectives

a. Improve our understanding of the factors that affect our health and the development and treatment of certain diseases.

b. 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 to facilitate the prevention, diagnosis, treatment and management of diseases, especially in areas of unmet public health need.
Specific objectives

c. 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.

d. Make better use of opportunities to gather health data and use it in research and care, all while respecting relevant privacy legislation.

e. Develop ways of assessing the value of innovative, integrated health care solutions to patients, carers, healthcare professionals and organisations, and other stakeholders.
Call and Evaluation Planning
How does IHI work? Single-stage procedure

**Topic definition**
- Input from the wider research community (Third Parties Ideas)
- Industry partners
- Potential contributing partners
- Other stakeholders in the health community

**Advisory Groups Consultation**
- Science & Innovation Panel (S&IP)
- States' Representative Group (SRG)

**Single-Stage Submission of Full Proposal**
- Full Consortium (Public & Private Partners)

**Evaluation process**
- Academics
- Hospitals
- Regulators
- Patients’ Organisations
- SMEs
- For-profit legal entities (SMEs and larger enterprises)

**Granting phase**
- Signature of Grant Agreements (between project coordinator and IHI JU)
- Signature of Consortium Agreements (between partners)

**Project launch!**

Topic texts are approved by the IHI Governing Board, as part of the Annual Work Plan.
How does IHI work? Two-stage procedure

Topic definition
Advisory Groups Consultation
Science & Innovation Panel (S&IP)
States’ Representative Group (SRG)

Stage 1
Short proposal Submission
Evaluation process
Applicant consortium

Stage 2
Full proposal Submission
Applicant consortium
Pre-identified industry consortium

Granting phase

Academics
Hospitals
Regulators
Patients’ Organisations
SMEs
For-profit legal entities with an annual turnover of less than EUR 500 million

Signature of Consortium Agreements
(between partners)
Signature of Grant Agreements
(between project coordinator and IHI JU)

Topic texts are approved by the IHI Governing Board, as part of the Annual Work Plan
Eligibility rules: Participation

- Any legal entity or international organisation regardless of its place of establishment
- Costs related to contributions provided by participants shall amount to at least 45% of the total project cost.
- At least 3 independent legal entities established in a different Member State or Associated Country
- IHI specific eligibility criterion NOT applicable: stage one of two-stage calls:
- IKOP, IKAA or FC
- IMPORTANT! 1 legal entity should be established in a Member State
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

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

NOT eligible for funding:
- Pre-identified Industry Consortium
- Any legal entities which is:
  - A for-profit legal entity with an annual turnover of EUR 500 million or more
  - Any legal entities which is directly or indirectly controlling/or being controlled by for profit legal entities with an annual turnover of EUR 500 million or more.

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

See Horizon Europe programme guide
Apply for funding
Apply to IHI calls

- Calls 1 and 2 were launched on the 28th June 2022
- Full topic texts, along with recordings of information webinars and the brokerage event are available on the IHI website

Call 1 – single stage

- An innovative decision-support system for improved care pathways for patients with neurodegenerative diseases and comorbidities.”

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

- Personalised oncology: Innovative people-centred, multi-modal therapies against cancer

- Access and integration of heterogeneous health data for improved health care in diseases areas of high unmet public health need
1- An innovative decision-support system for improved care pathways for patients with neurodegenerative diseases and comorbidities

- **Challenge**: Most patients with neurodegenerative disease have comorbid conditions and polypharmacy. A more holistic approach across medical specialties silos is needed to improve interventions and better manage these patients. Crucial to consider the patient (and carer) perspective and quality of life aspects.

- **Scope**: Create solutions to translate what is essentially a heterogeneous and fragmented set of complex, measurable and analysable data elements into a clinical decision support system to better guide patients in the healthcare pathway.

- **Expected outcomes**: Enhanced, and more reliable tools and methods for (near) real time feedback on health interventions, supported by a sustainable digital platform and a collaboration framework across specialties and stakeholders for long-term benefits to patients and healthcare systems.
2- Next generation imaging and image-guided diagnosis and therapy for cancer

● **Challenge:** An optimized image-based care path from early diagnosis and screening to treatment and follow-up is essential to improve the outcome of cancer patients and help optimize clinical workflows and the cancer patients' journey. Next-generation imaging technologies and image-guided solutions as part of combined cancer therapies would be of high value in this context.

● **Scope:** Pooling, linking, and using existing cancer patient imaging and other relevant data for development of robust AI/ML-based algorithms and enhancing of image-guided tools in clinical settings to assist and guide clinicians at the different steps of cancer care.

● **Expected outcomes:** More efficient patient-centric diagnosis, therapies, interventions with better outcomes for patients, simpler clinical workflows, reduced workload on staff, significant reduction of therapy and intervention time and shorter recovery times/hospital stays.
3- Personalised oncology: Innovative people-centred, multi-modal therapies against cancer

- **Challenge:** Different treatment modalities are available for various cancers, however, the differing biology of cancers as well as the differing efficacy of treatment modalities dictate rather patient-specific approaches. This requires a biomarker-guided multi-modal approach based on imaging, phenotype, genomics, in vitro diagnostics, co-morbidities, clinical and real-world data and combining knowledge and experience of different industry sectors.

- **Scope:** A biomarker-guided multi-modal personalised oncology, based on imaging, phenotype, genomics, in vitro diagnostics, co-morbidities, clinical and real-world data as well as the development of new health technologies integrated with current therapy concepts, for multi-modal therapies personalized to the needs of the individual patient.

- **Expected outcomes:** A Platform, standards and demonstration of how the benefits of health technology convergence can be harnessed to enable personalised cancer therapy and improve multi-modal therapy for better patient outcomes.
4- Access and integration of heterogeneous health data for improved health care in disease areas of high unmet public health need.

- **Challenge:** Accessing, integrating & analysing the many data that could be harnessed for use in healthcare delivery and research to maximise the value for patient care and research is extremely challenging. This is especially important for novel datasets, e.g., datasets that are not already accessible for the purpose of medical decision-making.

- **Scope:** to provide a scalable platform for the seamless integration or linkage of these diverse data and develop tools to allow the data to be used in clinical care, patient self-management and research in disease areas of high unmet public health.

- **Expected outcomes:** long term access to diverse data via linkage and integration of novel and cross-sectoral sources, development of tools and clinical support systems that facilitate disease self-management, empower joint health care professional - patient decision making & help delivering better health care services.
Call 2 – two stage

- Cardiovascular diseases - Improved prediction, prevention, diagnosis and monitoring
- Setting a harmonised methodology to promote uptake of Early Feasibility Studies for clinical and innovation excellence in the European Union
1- Cardiovascular diseases - Improved prediction, prevention, diagnosis and monitoring

● **Challenge:** Cardiovascular disease (CVD) is one of the leading causes of death globally with increasing prevalence of well-established CVD risk factors such as obesity, diabetes, and chronic kidney disease. There is a need for a more personalised approach and cardiovascular risk assessment.

● **Scope:** to provide tools for earlier diagnosis of atherosclerosis (ASCVD) & heart failure (HF), and identification of patients at risk incl. biomarker tools to assess changes in risk and measure response to intervention. To integrate patient data from various sources e.g. by a federated database, to provide the basis for prediction models to help detecting, monitoring and treating ASCVD and HF in an individual patient.

● **Expected outcomes:** Provide the basis for better primary and secondary prevention of CVD via prediction models to improve stratification of patients and reveal insights to achieving earlier intervention.
2- Setting a harmonised methodology to promote uptake of Early Feasibility Studies for clinical and innovation excellence in the European Union

● **Challenge**: Lengthy & incremental development process of innovative/breakthrough health technologies from bench to market launch (iterative testing & evidence generation). Early feasibility studies (EFS) could facilitate this process by capturing early relevant information and by optimising design before running a large clinical investigation.

● **Scope**: To develop a methodological framework for EFS compliant with EU regulations, easily accessible via permanent online portal with information on how to undertake such studies, the process and requirements to follow and fulfil, recommendations for best practices. To set up a stakeholder network to promote the conduct of EFS. To facilitate use-cases to inform, refine and validate the framework.

● **Expected outcomes**: Methodology for EFS, to facilitate compliance with relevant legislation applicable in the EU, and a stakeholder network that will ultimately contribute to improve patients’ access to health technologies and to a smoother development process.
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# Call 2 - two-stage – Timelines

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## 2 types of calls for proposals

### single-stage

- Broad topic, not specific to one single product/technology/solution
- Private Members apply simultaneously with Public Members in mixed consortia
- Due to its openness and competitive character, private members can receive funding
- Pharma companies will abstain from requesting funding
- Industry partners build consortia with public partners (like in HE regular calls)
- Proposed budgets must include at least 45% in-kind contribution (e.g., 10 mil total budget: at least 4.5 mil in-kind provided by members of founding associations)

### 2-stage

- Topics and budget are determined by Private Members
- Applicant consortia of beneficiaries requesting funding submit a short proposal at stage 1
- The successful applicant consortium joins with the pre-identified industry consortium the second stage
- Private Members are not eligible for funding
- In fact, no funding will be made available for any company with annual turnover > 500M
- No requirement for applicant consortia to provide in-kind contributions in a two stage process
Shape our future research and get involved

• **Become an evaluator / independent observer**

• **Join the Patient Pool** (to be re-opened later this year)

• **Propose new ideas**

• **Contribute at programme level:**
  - join an industry association
  - become a Contributing Partner

• **Apply to IHI Calls**
Data, new technologies and digitalisation

- Data, new technologies, digitalisation and cross-sectoral collaboration will be at the core of IHI projects
- Build upon experience of IMI1 and IMI2
- IHI focus will be to go beyond medicines development and support the translation of scientific progress, technology advances and big data opportunities to improve health care
  - Particular focus on the patient journey - prevention, diagnosis, treatment and management of diseases/conditions
- IHI office is a neutral platform that allows researchers, industries (large and small, different sectors), regulatory bodies, healthcare providers, healthcare professionals, patients, carers to work together
Stay in touch

Innovative Health Initiative

We are an EU public-private partnership funding health research and innovation

Apply for funding

Find out about our potential future call themes.

Why apply for IHI funding?

How to find partners for your consortium.

Shape our future research

Apply to be our next Executive Director (deadline: 14 March)

Become a contributing partner.

ihi.europa.eu
Stay in touch

● Sign up for our monthly newsletter: www.ihi.europa.eu/news-events/newsletter

● Follow us on Twitter: @IHI_Europe

● Follow us on LinkedIn: Innovative Health Initiative (IHI)

● Questions? E-mail us: infodesk@ihi.europa.eu
Thank you for your attention