



Introduzione alla Innovative Health Initiative- IHI

Elisabetta Vaudano DVM, PhD
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Contenuto di questa presentazione

- Introduzione a IHI
- L'Agenda Strategica per la Ricerca e Innovazione di IHI (SRIA)
- Governance
- Influenza la nostra ricerca futura
- Fai domanda per i nostri fondi di ricerca

WHAT IS IHI?



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.

FROM IMI TO IHI



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.

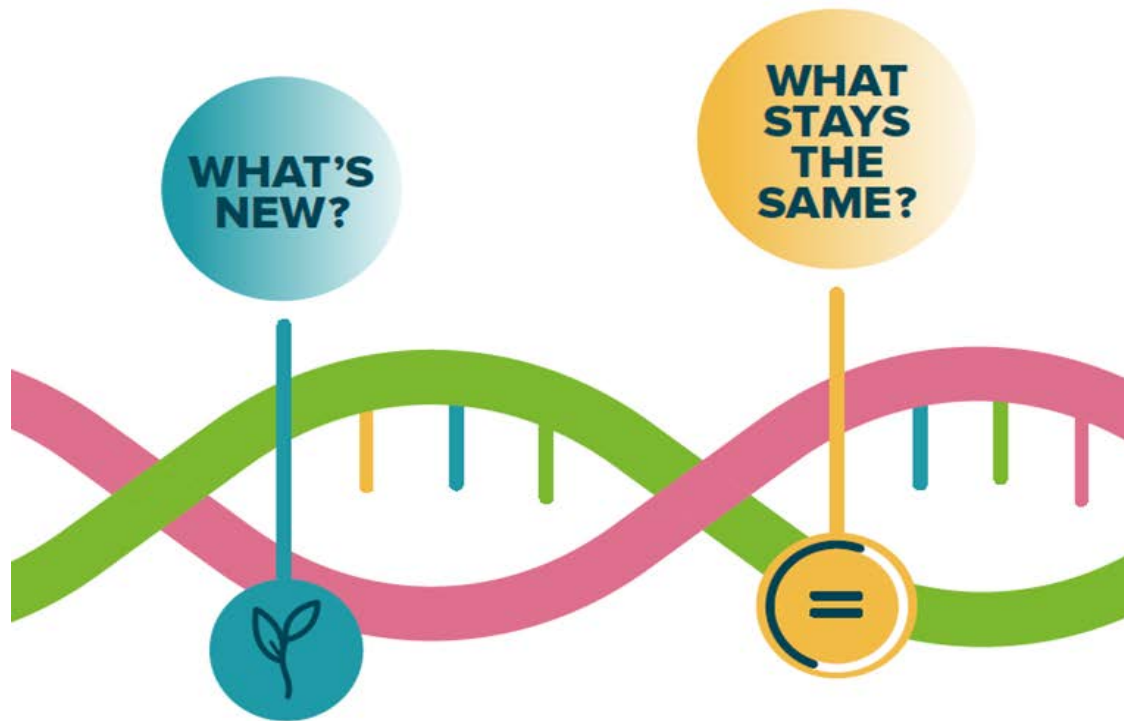
IHI PARTNERS



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**



- 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.

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

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 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.



L'Agenda Strategica per la Ricerca e Innovazione di IHI (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.

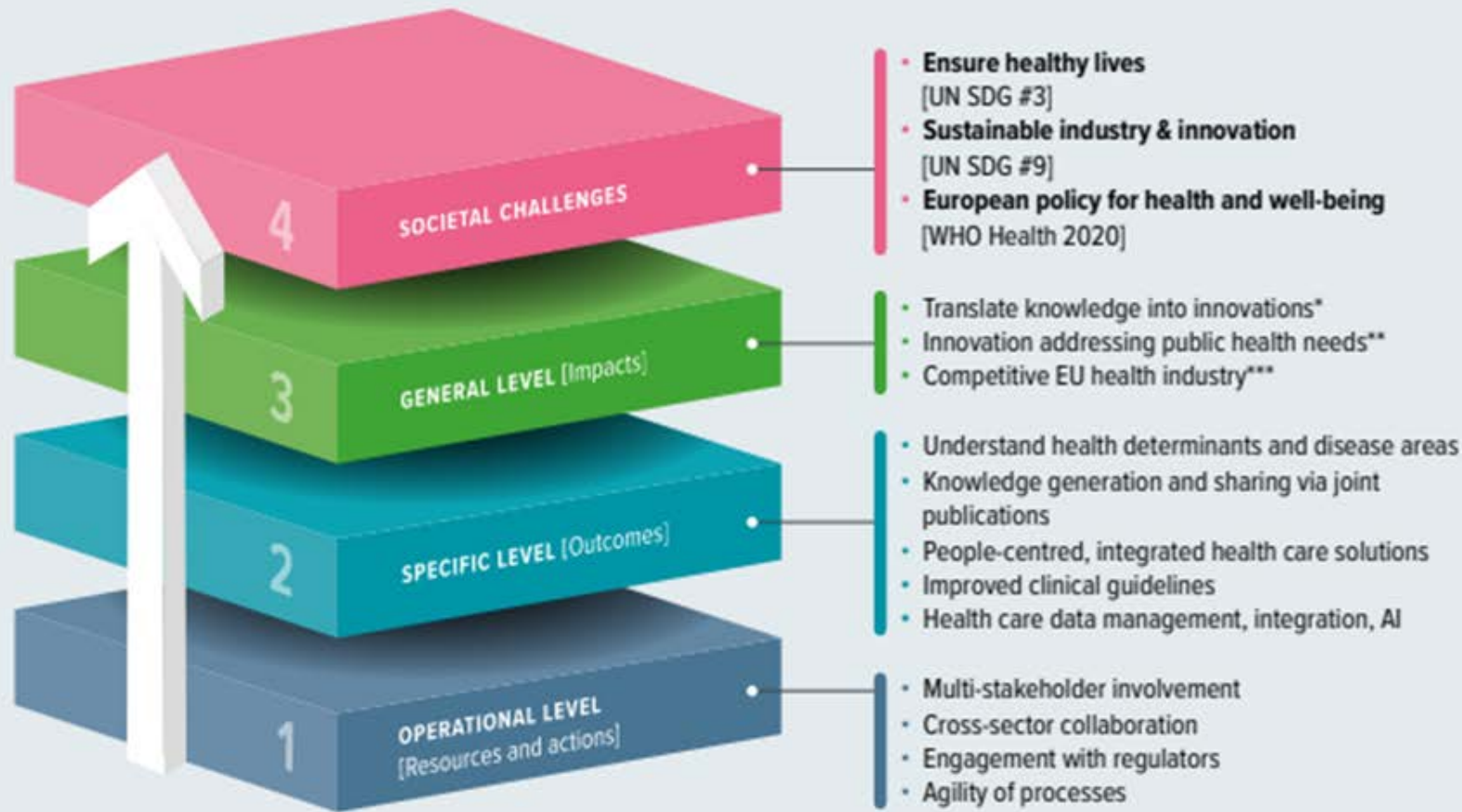
What's in the SRIA?

For each **specific objective**, the SRIA explains in detail:

- the current challenges
- how IHI could address them
- suggests potential outputs for IHI projects
- describes the medium to long-term impacts

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

IHI vision: contribute to societal challenges through ...



* IHI General Objective 1:
Contribute toward the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations

** IHI General Objective 2:
Foster the development of safe, effective, people-centric and cost-effective innovations that respond to strategic unmet public health needs

***IHI General Objective 3:
Drive cross-sectoral health innovation for a globally competitive European health industry

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 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.

How call topics are generated

Council Regulation (EU) 2021/2085

Strategic Research and Innovation
Agenda (SRIA)

Ideas for call topics

Annual Work Programme (AWP). Includes
the annual scientific priorities & call topics

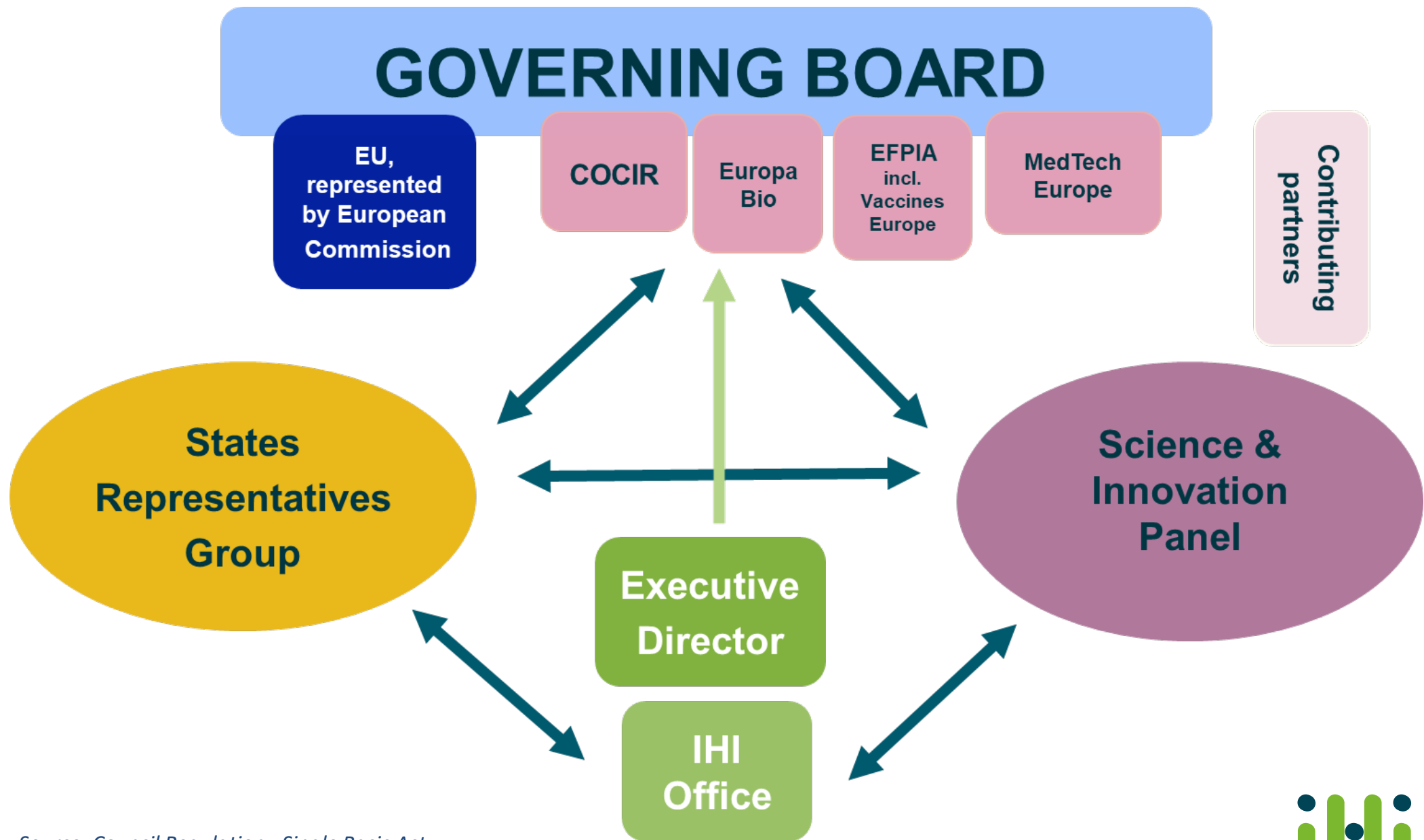
SIP review

Consultation with
advisory bodies
(SIP & SRG)

AWP adopted by IHI Governing Board



Governance



Source: Council Regulation - Single Basic Act

Science & Innovation Panel (SIP)

Why do we need the SIP?

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

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)

Representatives
appointed by
own body

Chair

4 members
Scientific community

Representatives
appointed via
EoI Call

(up to) 6 members
Stakeholders involved in healthcare (e.g. patients, health care professionals, healthcare providers, regulatory bodies, HTA, payers...)

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

- Sibilila 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)

- 
- Influenza la nostra ricerca futura

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 register on the Horizon Europe Funding & Tender Opportunities portal

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

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.

SOON!!!

Send us your ideas for IHI projects

- Many ideas for call topics come from our partners (industry members and the European Commission) and from contributing partners, but **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;
 - why they need a cross-sectoral public-private partnership.
- Ideas will be assessed by the IHI Programme Office and governance bodies.
- We're working on a platform and procedures to make it easy for people to submit call topic ideas. Once available, information will be placed on our website.

Get involved at programme level

- **Join one of the industry trade associations** who are IHI founding members: COCIR, EFPIA, EuropaBio, MedTech Europe, Vaccines Europe
- **Apply to become an IHI contributing partner** (similar to the status of IMI2 associated partner)

Become a Contributing Partner

Organisations that want to invest in IHI without becoming full members. Similar to IMI2 Associated Partners.

Who?

- Any country, international organisation or legal entity that wants to contribute to the IHI objectives can apply
exception: members / affiliates of IHI industry partners).

What?

- Contributing partners invest their own resources (staff time / laboratories / data / cash) in a specific IHI project(s). Contributions work in a similar way to those from industry partners.

Become a Contributing Partner

How?

- Apply via 'letter of endorsement' to IHI Governing Board – contact the IHI Programme Office for details!

Why?

- Leverage funding: In many cases, contributions from contributing partners can be matched by EU contributions. In total, **the EU can match up to EUR 200 million from contributing partners.**
- Influence research: As an investor in a project, you will be able to influence it from the earliest stages.
- Networking: As an IHI contributing partner, you will be part of the wider collaborative health innovation ecosystem that we are creating.
- Benefits of scale: IHI expects to launch ambitious, large-scale, cross-sector projects addressing major challenges in health research. Working at scale in this way increases the likelihood of the projects having a real impact.





Fai domanda per i nostri
fondi di ricerca

Apply to IHI calls

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

- The first calls should be launched **by the end of June 2022**
- Participate in the info-days, brokerage events and webinars organised up to Call launch

Read more about the topic ideas

www.ih.europa.eu/apply-funding/future-opportunities

**NUOVE INFORMAZIONI AGGIORNATE SARANNO
DISPONIBILI MOLTO PRESTO SU QUESTA PAGINA**

Eligibility rules: participation



Any legal entity or international organisation regardless of its place of establishment



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:

NEW

Costs related to contributions provided by participants shall amount to at least 45% of the total project cost.

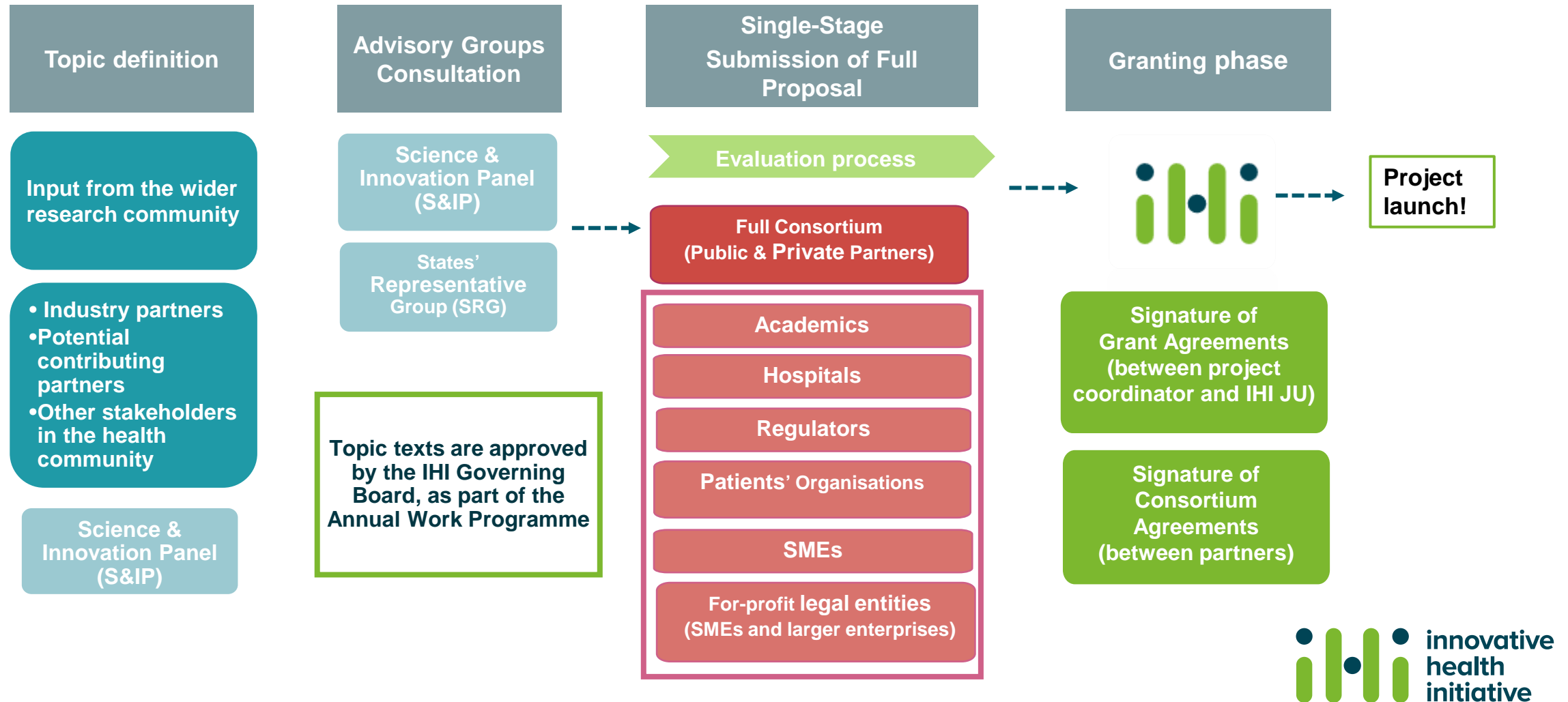
NEW

IMPORTANT!

1 legal entity should be established in a Member State

IKOP, IKAA or FC

How does IHI work? single-stage procedure



Potential future topics

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
- Precision oncology: Innovative patient-centric, 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:** patients with neurodegenerative disease often have comorbid conditions (e.g. cardiovascular disease, diabetes) and are treated with many drugs, which creates a highly complex system that needs better understanding. A more holistic approach with thinking beyond traditional medical specialties silos is needed to improve interventions and better manage these patients. Crucial to consider the patient perspective and quality of life aspects.
- **Scope:** the eventual topic under this theme will aim to establish projects that would deliver 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:** to better guide such complicate patient populations and their doctors in an individualised manner through the care pathway towards improved health.

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

- **Challenge:** personalised image driven diagnosis, prognosis and therapy of cancer patients needs to be enhanced by innovative solutions. This requires further enhancement of cancer patient imaging and other relevant data sources as well as artificial intelligence/machine learning (AI/ML)-enabled imaging and image-guided systems.
- **Scope:** the eventual topic under this theme will aim to establish projects that would contribute to providing better AI/ML-supported tools and image-guided assistance for 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- Personalized oncology: Innovative patient-centric, multi-modal therapies against cancer

- **Challenge:** there is a need to deliver a more patient-centric precision therapy in oncology. 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:** the eventual topic under this theme will aim to establish projects that will pursue different therapeutic strategies and combine at least 2 cancer treating modalities, evaluating aspects such as the sequencing, timing and dosing of therapies to maximise treatment effects with minimal toxicity and complications of normal tissue.
- **Expected outcomes:** facilitate the development of new health technologies & their integration with (possibly adapted) current therapy concepts, to create and explore multi-modal therapies personalised to the needs of the individual patient.

4- Access and integration of heterogeneous health data for improved health care in diseases areas of high unmet public health need.

- **Challenge:** there is a need for a scalable, open platform to access and integrate data from diverse sources (clinical data, patient reported outcome measures, data generated by digital technologies) in areas of high unmet public health need. This is especially important for novel datasets, e.g. datasets that are not already accessible for the purpose of medical decision-making.
- **Scope:** the eventual topic under this theme will aim to establish projects that based on these data & platform should develop patient-centred tools and clinical decision support systems that are shown of added value compared to the standard of care through a use case applied to an area of unmet public health need.
- **Expected outcomes:** 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.

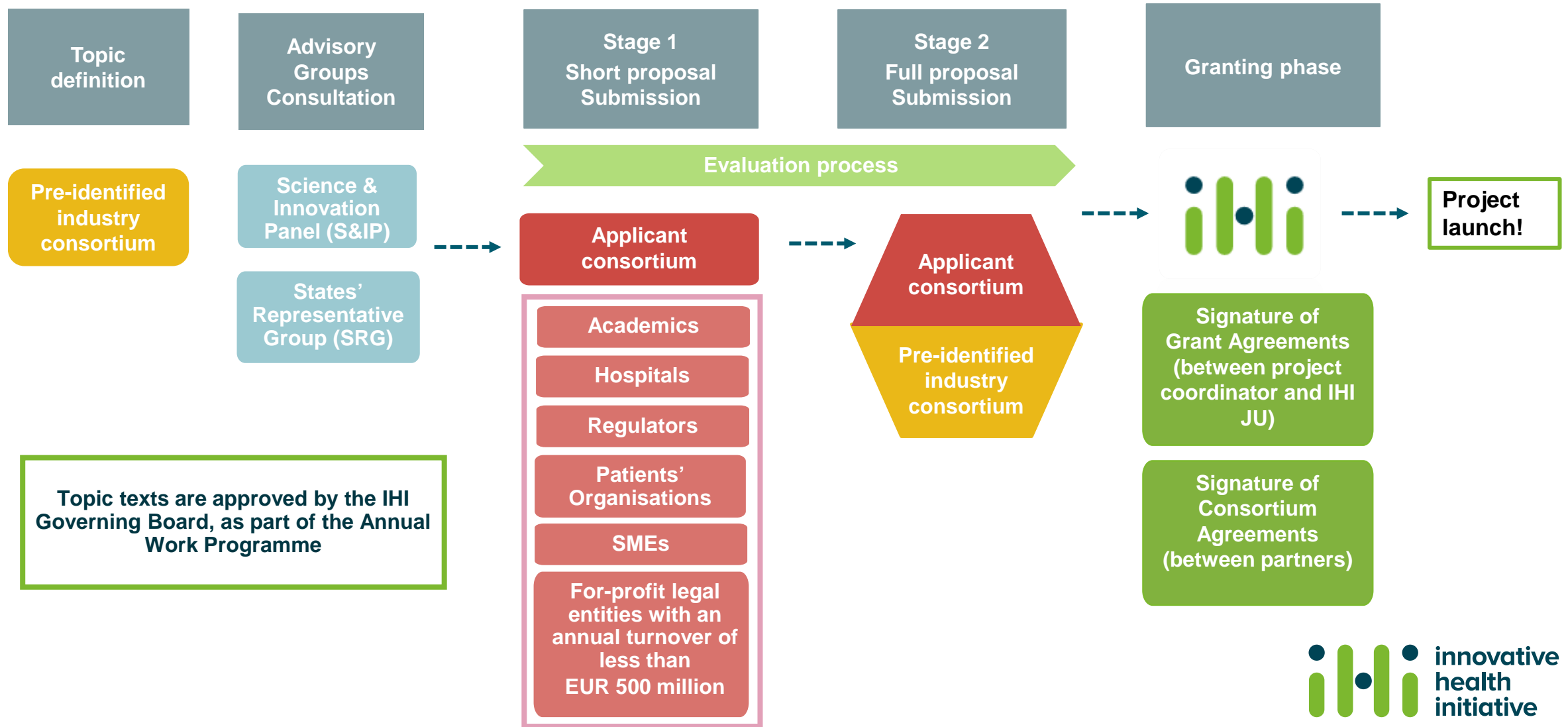
Call 1 – single stage – Indicative timelines



Eligibility rules: funding for single-stage Calls



How does IHI work? two-stage procedure



Potential future topics

Call 2 – two stage

- Cardiovascular diseases - Improved prediction, prevention, diagnosis and monitoring
- Setting a harmonized 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:** cardio-metabolic diseases are a major burden for patients, care partners and society. Shared risk factors of cardiovascular diseases are still often not diagnosed or addressed → great need for better diagnosis, prediction & prevention, and monitoring.
- **Scope:** increased availability & ability to link more traditional and newer types of health data (e.g. diagnostic screenings, in vitro diagnostics, 'omic' molecular measurement technologies, wearable devices and digital health applications) provide an opportunity for detecting early signs of potential pathologies/health conditions, as well as risk factors. Integration of these datasets will enable more timely diagnosis as well as detection of currently undiagnosed conditions, thereby paving the way for better health outcomes.
- **Expected outcomes:** results will generate combined biomarkers to identify citizens at risk who are currently not detected, and patients at risk of fast progression of disease with an intended focus on atherosclerosis and heart failure including their secondary manifestations.

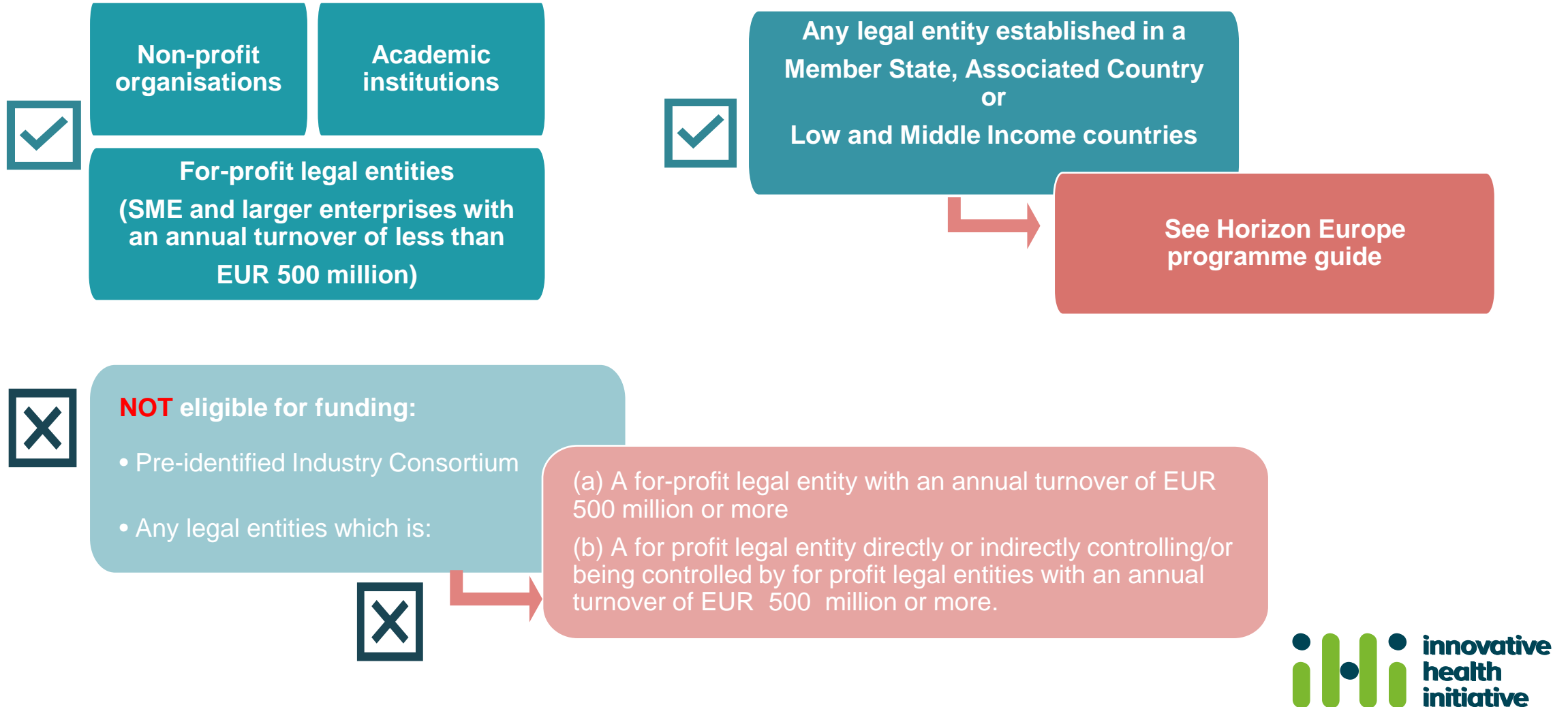
2- Setting a harmonized methodology to promote uptake of Early Feasibility Studies for clinical and innovation excellence in the European Union

- **Challenge:** the development of innovative / breakthrough health technologies takes a long time from bench to market launch and is incremental as to the design and intervention procedure.
- **Scope:** early testing through early feasibility studies (EFS) could facilitate the transition towards pivotal studies by optimising the design of clinical investigations that would in turn facilitate patient access to potentially beneficial technologies including digital technologies. EFS are not yet widely taken up in the EU.
- **Expected outcomes:** the project should contribute to the development of a methodological framework that will harmonise approaches and facilitate the uptake of early feasibility studies in the EU. It will also look at facilitating the interactions between the different stakeholders that would contribute to a strengthened patient-centred evidence generation and innovation ecosystem.

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

Eligibility rules: funding for two-stage Calls



The UK's association to Horizon Europe

- UK entities can participate in the first calls for proposals of Horizon Europe
- The General Annexes attached to the main Horizon Europe work programme (2021-2022) ensure that UK applicants are treated as if the UK is an associated country throughout the process, **from admissibility and eligibility to evaluation, up until the preparation of grant agreements.**
- **Grant agreements can only be signed if the association has come into force.**
- Find out more in the European Commission Q&A on the UK's participation in Horizon Europe:
https://ec.europa.eu/info/sites/default/files/research_and_innovation/strategy_on_research_and_innovation/documents/ec_rtd_uk-participation-in-horizon-europe.pdf

Intellectual Property Rights in IHI projects

- Horizon Europe legal basis applies (no specific derogations for IHI)
- IHI IPR rules derived from:
 - Horizon Europe Model Grant Agreement (MGA) Article 16;
 - supplemented by specific rules identified in HE MGA Annex V and;
 - where relevant, the applicable call conditions.
- IHI maintains right to object to transfers of ownership of results or to grants of exclusive licences.
- Results Ownership List ('ROL') to be submitted at project end as part of final periodic report listing all results and ownership of them (including joint ownership structures).

Intellectual Property Rights in IHI projects

- Emphasis on Exploitation and Open Science:
 - HE MGA integrates Open Science dissemination model;
 - Affordable Access Provisions can, when provided for in the call conditions, introduce additional exploitation obligations for relevant IHI topics;
 - Unexploited project results can be matched with interested parties via the Horizon Results platform.
- Some notable Access Rights changes from IMI2 JU to IHI JU^{*}
 - Access Rights are now consistent with Horizon Europe MGA;
 - No third party access rights after project end for research use of results.

^{*} Project IPR specificities to be agreed amongst all parties and detailed in the project Consortium Agreement

IHI calls – find out more & find partners

You'll need to build or join a consortium!

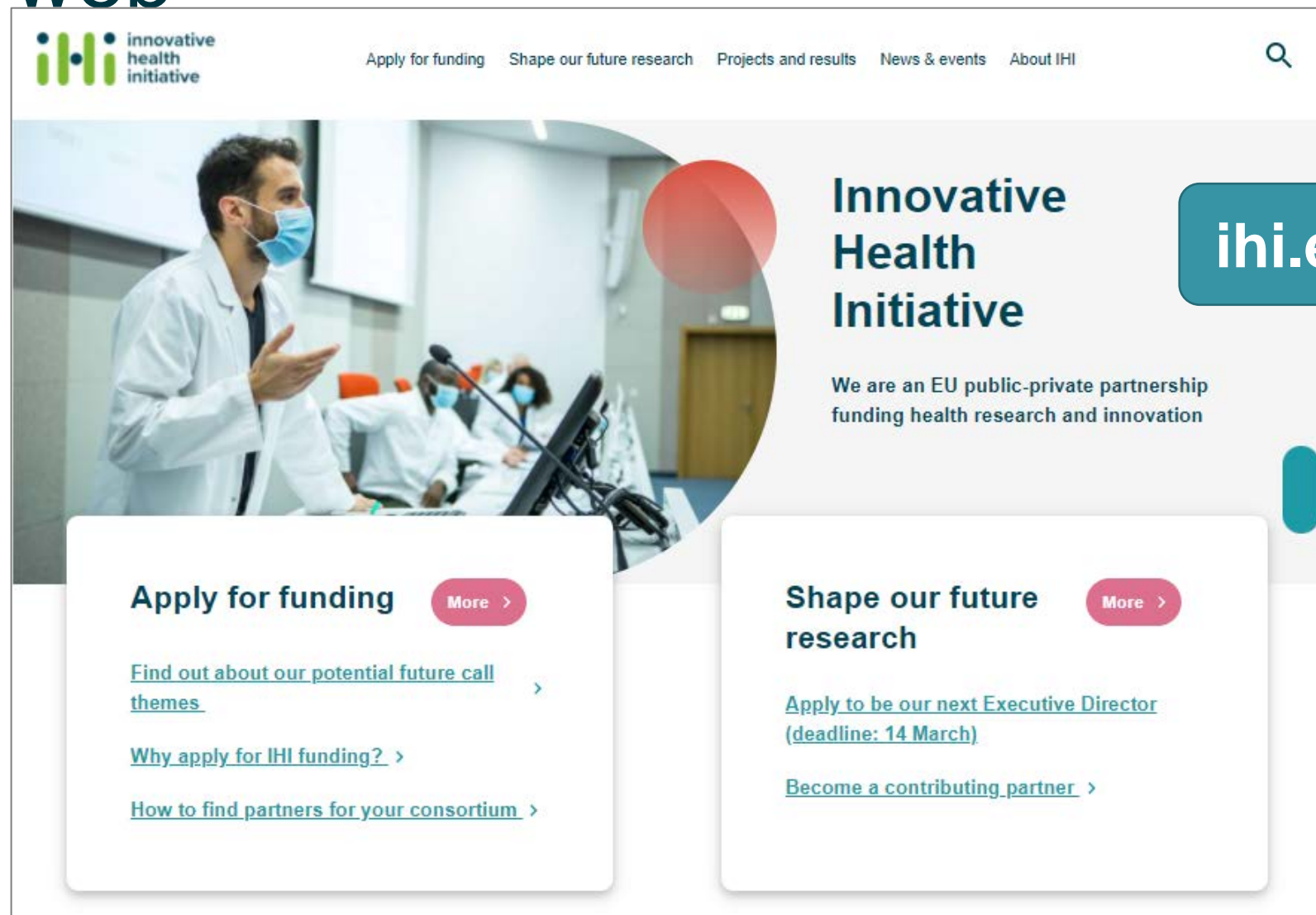
- Read the draft call texts as soon as they're published and start networking early
- Sign up for our webinars on the call topics & our rules and procedures
- Look out for our brokerage event!
- Use online partner search tools (e.g. on the Funding & Tenders portal)

More tips: www.ihi.europa.eu/apply-funding/find-partners

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.

Consulta regolarmente la nostra pagina web



The screenshot shows the homepage of the Innovative Health Initiative (IHI) website. At the top left is the IHI logo, and to its right is a navigation menu with links: 'Apply for funding', 'Shape our future research', 'Projects and results', 'News & events', and 'About IHI'. A search icon is located at the top right. The main banner features a circular image of a man in a white lab coat and blue face mask speaking at a podium. To the right of the image, the text reads 'Innovative Health Initiative' in large bold letters, followed by 'We are an EU public-private partnership funding health research and innovation'. Below the banner are two white boxes with rounded corners. The left box is titled 'Apply for funding' and contains three links: 'Find out about our potential future call themes', 'Why apply for IHI funding?', and 'How to find partners for your consortium'. The right box is titled 'Shape our future research' and contains two links: 'Apply to be our next Executive Director (deadline: 14 March)' and 'Become a contributing partner'. Both boxes have a 'More >' button in a pink pill shape. A teal pill-shaped button with the text 'ihi.europa.eu' is overlaid on the right side of the banner.

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[Apply for funding](#) [Shape our future research](#) [Projects and results](#) [News & events](#) [About IHI](#)

Innovative Health Initiative

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

Apply for funding [More >](#)

[Find out about our potential future call themes](#) >

[Why apply for IHI funding?](#) >

[How to find partners for your consortium](#) >

Shape our future research [More >](#)

[Apply to be our next Executive Director \(deadline: 14 March\)](#)

[Become a contributing partner](#) >

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Fonti di informazione e contatti

- Sign up for our monthly newsletter: www.ihl.europa.eu/news-events/newsletter
- Follow us on Twitter: [@IHI_Europe](https://twitter.com/IHI_Europe)
- Follow us on LinkedIn: [Innovative Health Initiative \(IHI\)](https://www.linkedin.com/company/Innovative+Health+Initiative+(IHI))
- Questions? E-mail us: infodesk@ihl.europa.eu



Grazie per la vostra attenzione!

ihi.europa.eu

