IHI Call 13: Shaping the Future of European Healthcare Innovation

Strategic presentation for Federfarma | Rome, Italy

6 JULY 2026

Alessandro Chiodini

innovative health initiative

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.

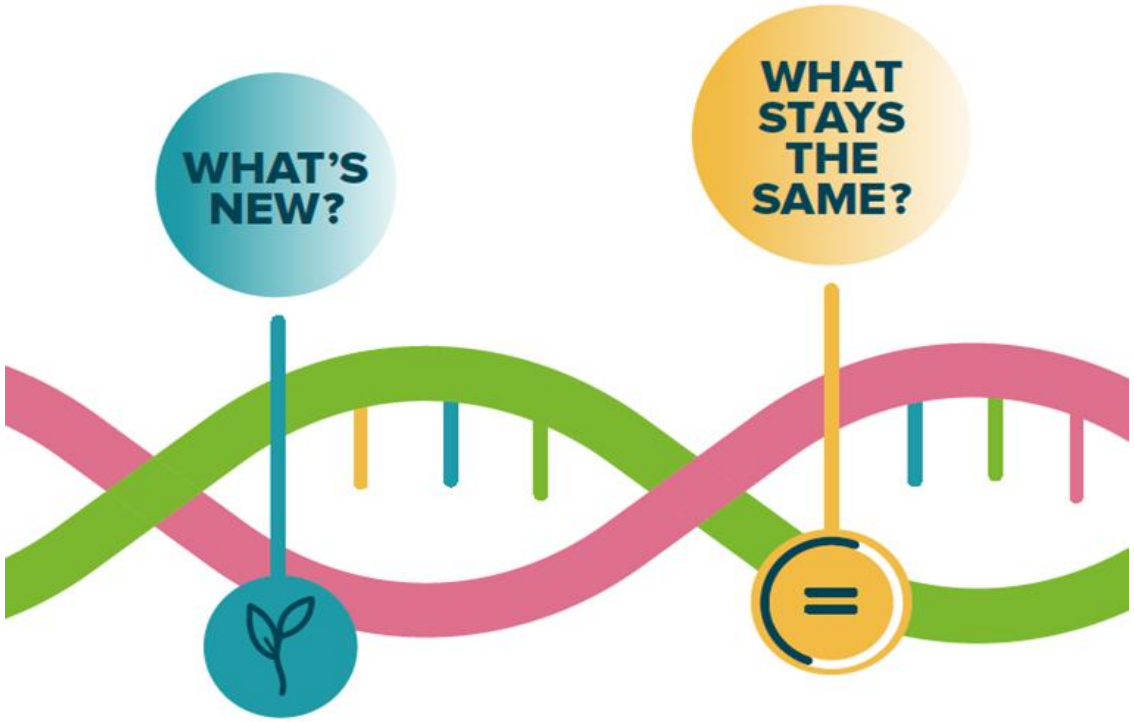
IHI will build on the extensive experience of **IMI's 14 years and almost 200 projects** to build an interdisciplinary, sustainable, patient-centric health research partnership to help transform patients' lives.

The industry members that make up the new partnership are:

- COCIR
- EFPIA
- EuropaBio
- MedTech Europe
- Vaccines Europe

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

innovative health initiative



- 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

innovative health initiative

Summary

European HealthCare Incubator Network

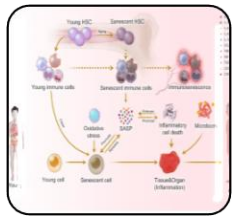
Funding: €35M, Duration: 60 months. Supports early-stage healthcare companies developing transformative technologies with regulatory and business development aid.

AI Toxicology Model

Funding: €9M + €7.3M in-kind, Duration: 60 months. Develops AI models to reduce animal testing in drug safety studies and enhance regulatory confidence.

Immuno-science of Age-related Diseases

Funding: €9M + €9-10M in-kind, Duration: 60 months. Investigates immunosenescence and age-related diseases to develop diagnostics and therapies for elderly patients.



innovative health initiative

How do two-stage calls procedure work.

Call launch

Topic texts are approved by the IHI Governing Board, as part of the **Annual Work Programme**

Pre-identified industry Consortium at topic text

Stage 1

Short proposal Submission

Stage 2

Full proposal Submission

Evaluation process

Applicant consortium

- Academics
- Hospitals
- Regulators
- Patients' Organisations
- SMEs

For-profit legal entities with an annual turnover of less than EUR 500 million

Applicant Consortium

Pre-identified industry consortium

Granting phase

Signature of Grant Agreements

(between project coordinator and IHI JU)

Signature of Consortium Agreements

(between partners)

Project launch!

Structured and transparent process

Inclusive multi-stakeholder consortia

Rigorous evaluation

Driving impactful health innovation

innovative health initiative

TOPIC 1

EHCIN: Early-stage Health Care Innovation Network

A massive **€35 Million** investment to build a sustainable support ecosystem for Europe's most promising health startups and SMEs.

> Objective: Bridge the "Death Valley" gap for health-tech innovators by providing integrated financial and strategic support.

innovative health initiative

Expected Outcomes

BUILDING THE FUTURE OF HEALTHCARE INNOVATION TOGETHER

ACADEMIA | INDUSTRY | INVESTORS

01 **Establish a sustainable, pan-European incubator network**
uniting academia, industry, and investors to support early-stage healthcare innovation

02 **Accelerate research-to-market pathways**
through mentorship, networking, funding, and access to infrastructure

03 **De-risk and strengthen start-ups,**
improving their attractiveness for private and public investment

04 **Provide agile funding via FSTP**
and facilitate collaboration with programmes like EIC

FSTP | eic European Innovation Council

05 **Deliver an industry-backed quality seal**
to validate high-potential start-ups

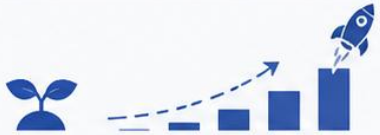
06 **Enable strategic partnerships**
across corporates, incubators, and venture capital

07 **Build a portfolio of investment-ready companies**
with enhanced business, technological, and market maturity

innovative health initiative

Scope

01 **Early-stage companies / start-ups:**
fast-growing ventures in early development phases



02 **Focus on TRL 3–5 technologies:**
from initial proof of concept to validated pre-clinical stage

03 **TRL 3–4:**
proof of concept and
early safety/feasibility demonstrated

04 **TRL 5:**
advanced pre-clinical validation,
regulatory pathways and
manufacturing defined

05 **Applies to medical devices and drugs**
at pre-clinical development stage

06 **Incubators:**
organisations providing mentorship,
infrastructure, training, and investor access

07 **Funders (public/private):**
investors offering capital and
strategic support (e.g. venture capital,
public programmes)

innovative health initiative

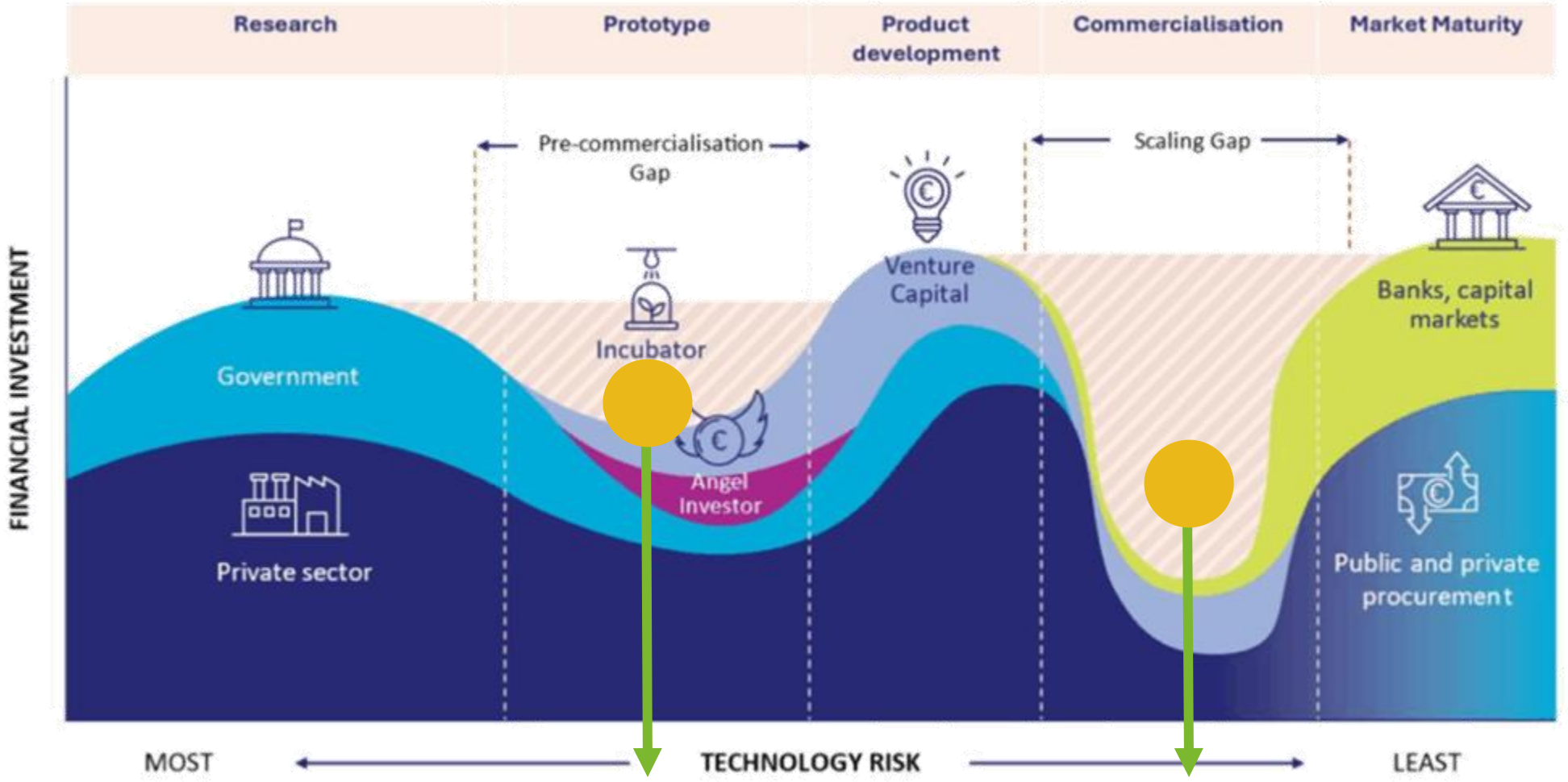
Objectives

1. **Build a pan-European, multi-sector incubator network**
   connecting start-ups with industry, funders, and experts
2. **Accelerate early-stage innovation** (TRL 3–5)
   through funding (FSTP) and direct industry engagement
3. **Select, fund, and monitor high-potential start-ups**
   via transparent EU-wide calls
4. **Provide a growth support programme:**
   mentorship, infrastructure, regulatory guidance, and business development
5. **Strengthen investment readiness and partnerships**
   with pharma, med-tech, and venture capital
6. **Ensure long-term sustainability**
   through governance, KPIs, impact monitoring, and a post-funding strategy
7. **Contribute to bridging the "valley of death"**
   and advancing healthcare innovation in Europe

CONNECT | ACCELERATE | SUPPORT | INVEST | SUSTAIN | IMPACT

innovative health initiative

The Startup Double Valley of Death



The Network

E.g. the Scaleup Europe Fund

innovative health initiative

Financial support to 3rd parties

Core funding mechanism to support **early-stage healthcare start-ups (TRL 3–5)**

At least **75% of total funding** allocated to start-ups via competitive open calls

Focus on **high-impact, unmet healthcare needs** and transformative technologies

Two-stage funding model (milestone-based):

STAGE 1

Initial grant:
€100k – €1M

»

STAGE 2

Follow-on grant:
up to **€1M** additional

Max
€2M
per start-up

Funding strictly for **core R&I activities** (e.g. validation, pre-clinical development)

Transparent selection based on **excellence, impact, and strategic relevance**

Managed by EHCIN with **strong governance, monitoring, and EU compliance**

innovative health initiative

Expected impacts

01 **Deliver innovative health solutions** addressing unmet public health needs

02 **Build a strong European pipeline** of validated start-ups integrated with EU initiatives

03 **Strengthen EU competitiveness** in healthcare R&D and innovation

04 **Establish a sustainable, pan-European incubator network** reducing fragmentation

05 **Enable data-driven and digital health solutions** (AI, big data, EHDS alignment)

06 **Increase investment readiness** via industry validation ("quality seal")

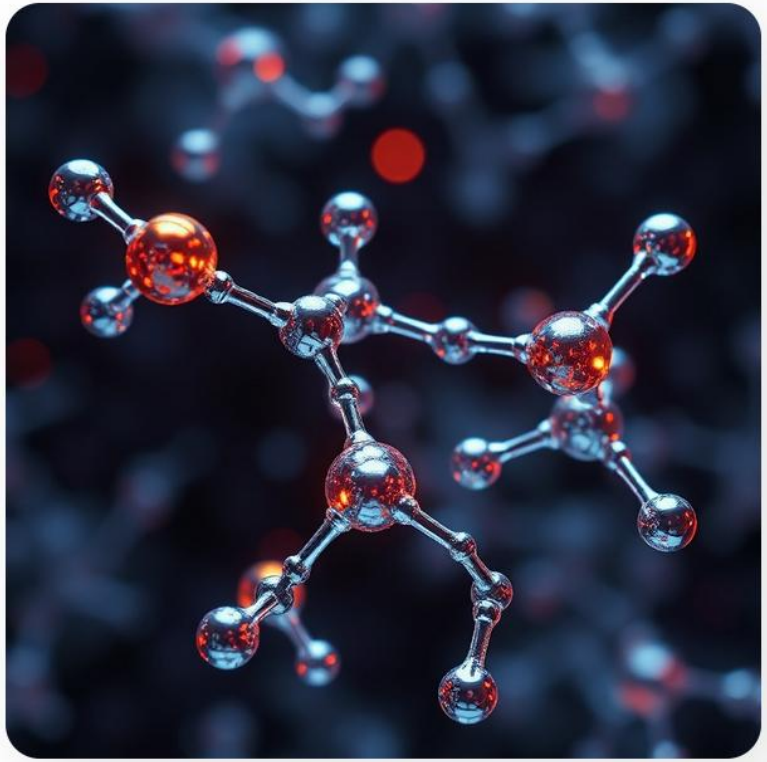
07 **Accelerate research-to-market translation** and scale-up pathways

08 **Create synergies with EU strategies and programmes,** maximising impact and avoiding duplication

innovative health initiative

TOPIC 2

AI Models for Regulatory Toxicology



Funding Breakdown

€9.0M
IHI FUNDING

+

€7.3M
PRIVATE IN-KIND

Developing **New Approach Methodologies (NAMs)** using Artificial Intelligence to predict drug safety and toxicology with unprecedented accuracy.

> **Focus:** Reducing reliance on animal testing while increasing clinical success rates.

innovative health initiative

Expected Outcomes

01 **Develop a validated AI foundation toxicology model**
for probabilistic safety predictions

02 **Enable reduction or waiver of second-species testing**
in chronic and sub-chronic studies

03 **Establish a standardised weight-of-evidence framework**
for consistent, transparent regulatory assessment

04 **Provide practical tools, templates, and training**
for real-world implementation

05 **Increase regulatory and industry confidence**
in AI- and NAM-based approaches

06 **Support faster, more efficient drug development**
while maintaining patient safety

innovative health initiative

Scope

01	**Address limitations of two-species animal testing** (cost, ethics, limited human relevance)	Lower costs and ethical responsibility
02	**Leverage AI and New Approach Methodologies (NAMs)** to enable second-species waivers	Enable NAM-based second-species waivers
03	**Develop a data-driven, standardised toxicology model** supported by a weight-of-evidence framework	Robust, transparent and science-based decisions
04	**Integrate diverse datasets** (in vivo, in vitro, omics, AI models, regulatory data)	Comprehensive, high-quality data foundation
05	**Ensure regulatory alignment and validation** (EMA, FDA) with long-term guideline impact	Regulatory trust and guideline transformation
06	**Use advanced AI methods** (probabilistic models, explainability, federated learning)	More accurate, explainable and generalizable models
07	**Foster cross-sector collaboration** (industry, academia, regulators)	Stronger partnerships, shared expertise, greater impact
08	**Aim to reduce animal testing, costs, and timelines** while improving patient safety and innovation	Better patient safety and faster innovation

BETTER SCIENCE → SMARTER DECISIONS → REGULATORY CONFIDENCE → STRONGER COLLABORATION → SAFER MEDICINES BETTER OUTCOMES

Advancing science. Protecting lives. Driving innovation.

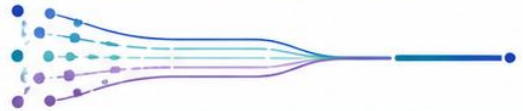
innovative health initiative

Objectives

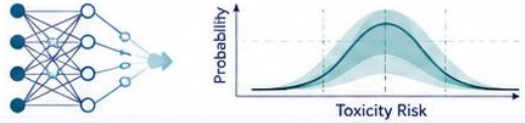
01 **Consolidate multi-source toxicology data**
(in vivo, in vitro, omics, PK, regulatory, structured & unstructured)

02 **Build a secure federated data platform**
enabling privacy-preserving, multi-organisation analysis

03 **Apply data harmonisation, representation learning, and multimodal integration**



04 Develop **advanced AI models** for **probabilistic** toxicity prediction with **uncertainty quantification**



05 Ensure **transparency, explainability**, and full **data provenance** for regulatory trust

06 **Establish a clear regulatory strategy** targeting **EMA/FDA validation** and future guideline evolution

07 Enable **NAM-based second-species waivers** and long-term expansion to **broader modalities**

High-quality, integrated data | Secure & privacy-preserving | AI-powered insights | Regulatory alignment | Multi-stakeholder collaboration | Better decisions, better outcomes

innovative health initiative

Expected impacts

TOPIC 3

Immuno-aging & Multi-omics

Decoding why the immune system ages and how this drives chronic diseases across the lifespan.

€9.0M	€9-10M
IHI FUNDING	IN-KIND ESTIMATE

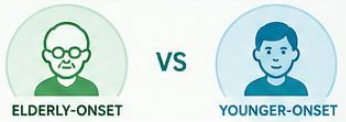
innovative health initiative

Expected Outcomes

01 Improved understanding of **causal links** between **aging and chronic inflammatory diseases**

02 **Predictive biomarkers** enabling early risk profiling and disease stratification

03 **Early detection and improved diagnostics,** distinguishing elderly-onset vs younger-onset disease

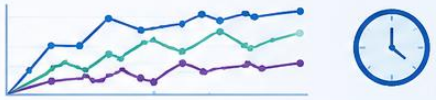


04 Advancement of **personalised and precision medicine,** reducing disease progression and costs

05 Development and **repurposing of targeted therapies** for aging populations

06 Integrated use of **biobanks, multi-omics, AI, and digital biomarkers** across cohorts

07 Better insight into **treatment response** and **age-related effectiveness**



08 Progress toward **regulatory acceptance** of digital biomarkers as endpoints

innovative health initiative

Scope

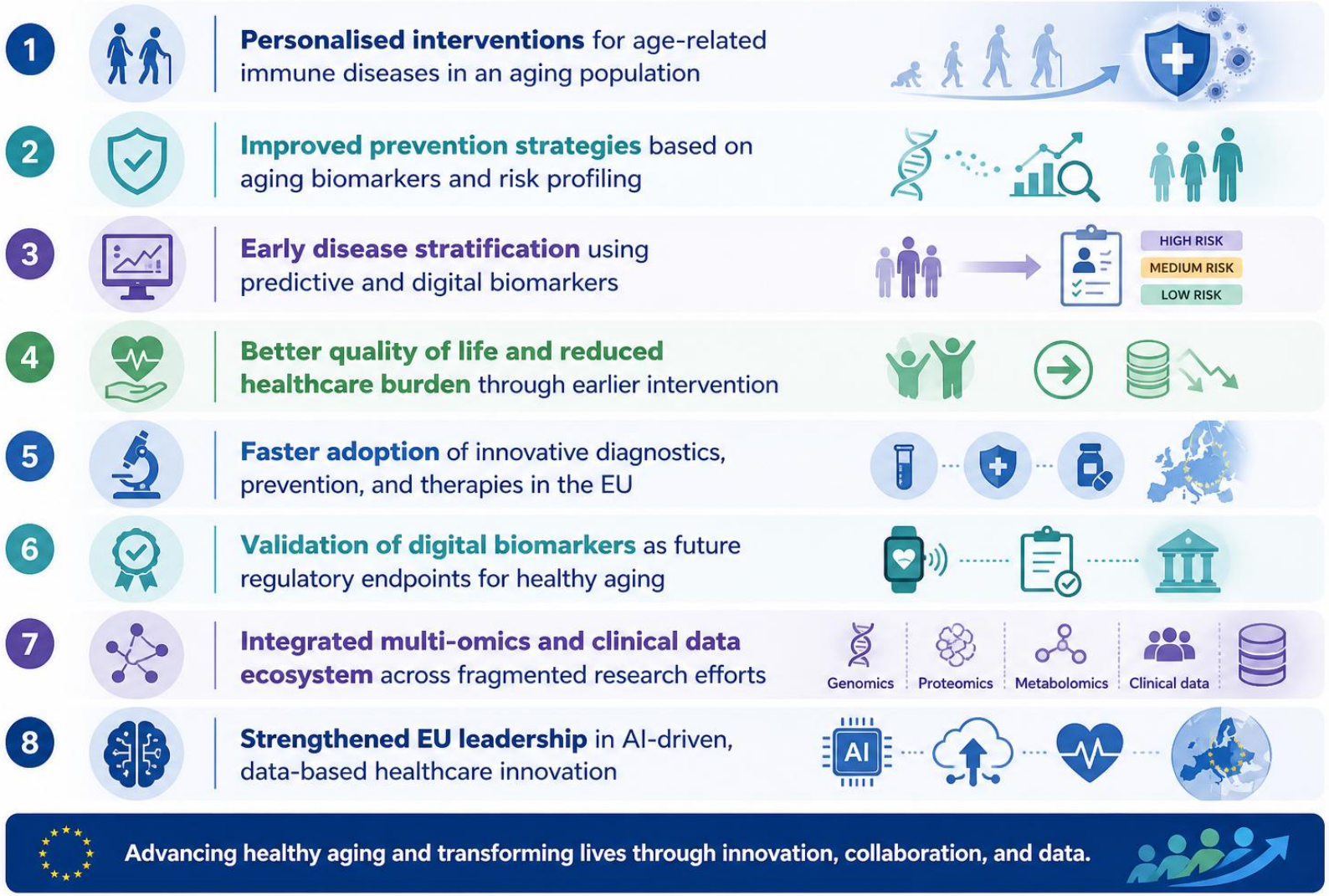
- Rapid global **population aging** → rise in chronic disease, multimorbidity, and poor health span
- Aging immune system (**immunosenescence + inflammaging**) drives disease susceptibility and severity
- Elderly-onset immune diseases may represent **distinct clinical and molecular entities**
- Key disease areas: **IBD, respiratory diseases,** and **rheumatoid/autoimmune disorders**
- Critical gap: limited understanding of **bidirectional link** between aging, immunity, and disease
- Aim: identify **biomarkers, mechanisms, and aging signatures** to enable precision prevention and treatment
- Leverage **multi-omics, AI, cohorts,** and **digital biomarkers** for integrated disease and aging analysis

Multi-omics | AI | Cohorts | Digital biomarkers

Goal: Unlock the biology of aging and immunity to improve health span and transform care for an aging population.

innovative health initiative

Expected Impacts



innovative health initiative

Why Apply? Strategic Edge

01 Pre-Competitive Edge

Work directly with competitors on common challenges, sharing risks and resources for foundational breakthroughs.

02 Regulatory Access

Direct dialogue with EMA and notified bodies within the project framework, reducing time to market.

03 Market Positioning

Validation of your technology by a consortium of European leaders provides immense commercial credibility.

04 Networking

Build long-term partnerships with Europe's premier hospitals, universities, and industry giants.

innovative health initiative

What to Do Next

Review Call Documentation

Carefully examine the detailed call information available on the IHI website to understand requirements and opportunities.

Identify Consortium Partners

Build a collaborative network of academic, industry, and SME partners aligned with the call objectives.

Assess Strategic Fit

Evaluate how participation aligns with your organization's goals and strategic priorities.

Prepare Expression of Interest

Develop and submit your expression of interest by the specified deadlines to participate in the call.

Conclusion & Next Steps

Why Apply to IHI Call 13?

- Unprecedented opportunity to shape European healthcare innovation.
- Substantial funding with significant industry in-kind contributions.
- Real-world impact from startup acceleration to elderly patient care.

Next Steps

1

1. Review

Review detailed call documentation on the IHI website.

2

2. Identify

Identify consortium partners across academia, industry, and SMEs.

3

3. Assess

Assess alignment with your organization's strategic priorities.

4

4. Prepare

Prepare an expression of interest for upcoming deadlines.

For more information on IHI Call 13, visit the Innovative Health Initiative website or contact your national IHI representative.

innovative health initiative

innovative health initiative

Alessandro Chiodini

06.07.2026 • Rome, Italy

COCIR Advancing Healthcare

efpia

EuropaBio The European Association for Bioindustries

MedTech Europe from diagnosis to cure

Vaccines Europe

Co-funded by the European Union