Spotlight on funding at EU level and ways of involving regulators in scientific projects
Innovative Health Initiative (IHI)

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29.09.2025 • EMA/HMA European Platform for Regulatory Science Research • virtual meeting

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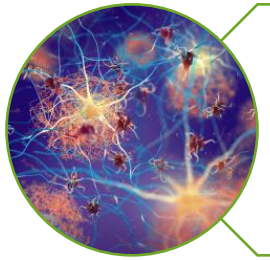
IHI: Bold collaborations, transforming health

Cross-sectorial nature of IHI : a unique platform for engaging a wide range of stakeholders – patients, researchers, healthcare providers, regulators & different industry sectors



Deliver **safe, effective health innovations** that cover the entire spectrum of care, particularly in areas where there is an unmet public health need

Turn health research and innovations **into real benefits** for patients and society

Make Europe's health industries **globally competitive**

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IHI experience

- Many consortia benefits from EMA services like ITF, advice from NCAs or other types of interactions with regulators
- Regulators involved in several projects as beneficiaries (e.g in 6 IHI projects) or in an advisory capacity

• 3 EMA Qualification Opinions

ProActive: PRO for COPD

PREFER: Framework for patients preference

Amypad: Centiloid measure of Amyloid PET to quantify brain amyloid deposition used for enrichment in clinical trials in Alzheimer

• 17 EMA Letters of Support

e.g Biomarker in AMD;, autism, chronic kidney disease, master protocol for T1 diabetes, digital mobility outcome as monitoring biomarker etc..

• Other relevant results

EHDEN; ConcePTION, GetReal;

ITCC-P4; c4c;

Vac2Vac;

Gravitate-Health

imi innovative medicines initiative **182 projects**

ihi innovative health initiative **39 projects**

Lessons learned

- Positive experience with regulatory support services offered by regulatory agencies

- Need for planning : understand regulatory landscape, develop a regulatory strategy and interaction plan (early & iterative, timelines), have regulatory expertise, resources (personal and financial), design a data management plan tailored.
  - Regulatory perspective embedded in IHI call topic text when relevant
  - In their proposals applicants should explain their regulatory strategy and interaction plan, when relevant
  - Regulatory considerations for IMI/IHI projects Guide for applicants and project consortia

- Amount of work required and data to be generated for regulatory endorsement often underestimated

- Awareness & sharing learnings

Publications from IMI projects e.g IDEA-FAST, Litmus, RADAR-AD, MOBILISE-D

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Why is maximising regulatory impact important?

- Filling research gaps and addressing complex regulatory science challenges
- Ensuring the translation of research into practical application to support R&D, inform decision-making and ultimately bring health innovation to people with unmet needs

    e.g.: biomarkers, endpoints, modelling tools

- Developing the science today needed to inform regulatory/HTA decision-making for tomorrow's innovations in medicines and technology
- Preparing grounds and pilot novel approaches to improve regulatory processes and future proof future legislation

    e.g e-labelling, AI in pharmacovigilance, regulatory sandbox

- Gaining new scientific insight and capacity building (sharing learnings/knowledge)
- Contributing to Europe competitiveness and global impact of cutting-edge research

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Next IHI funding opportunities

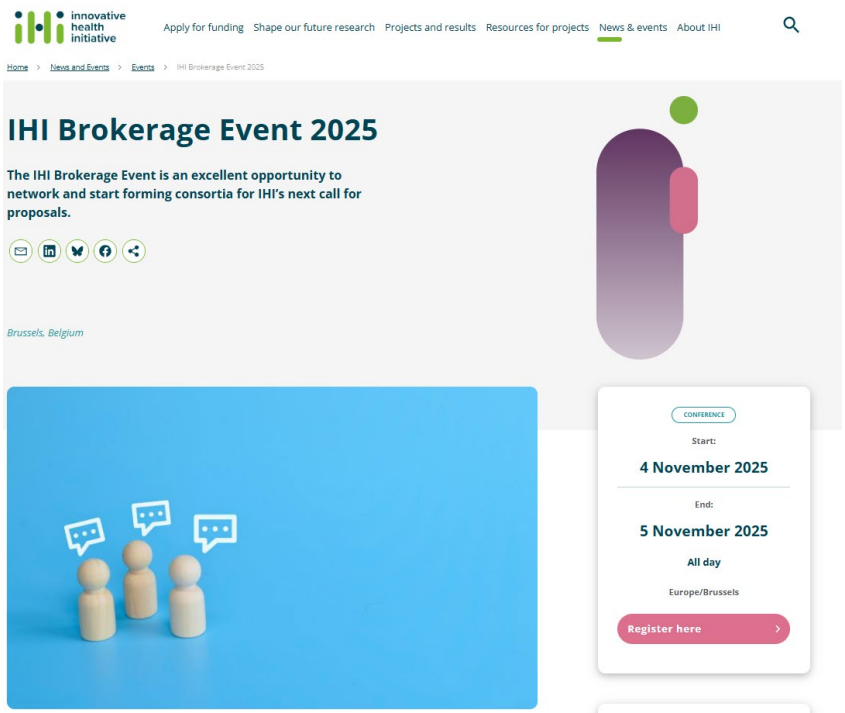
- **IHI applicant-driven call 12 to be launched in early 2026**

Broad scope to applicants to explore new opportunities for IHI projects in the IHI Strategic Research and Innovation Agenda, including projects contributing to regulatory science

More Information on IHI website

- **IHI Brokerage event**

Opportunities potential applicants to network and start forming consortia



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