IHI Call Days | Call 12

Unifying Europe’s clinical research ecosystem for faster access to innovation -

an IHI Public Private Partnership Proposal

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The Challenge – Europe is Losing Ground in Medical Innovation

FACTS

- Global clinical trial activity has increased by 38% over the past decade, yet **Europe's share has declined** from 22% to 12% and for cell- and gene-based therapies, from 25% to just 10%.
- Nearly **80% of trials are delayed** or fail to complete, and 11% of sites do not enroll a single patient.

WHY IS THIS?

- PATIENTS
  - → Access to community patients is limited, and one in three European **patients remains hesitant** to participate in clinical trials.
- GOVERNANCE, ETHICS, DATA RULES
  - → all are **fragmented**, which continues to slow approvals and hinder multinational trials.
- TRIAL SITES
  - → Growing constraints from **capacity limits, staff shortages, and lengthy contracting processes**.

How Europe Has Responded So Far

→ **ACT-EU (Accelerating Clinical Trials in the EU)**

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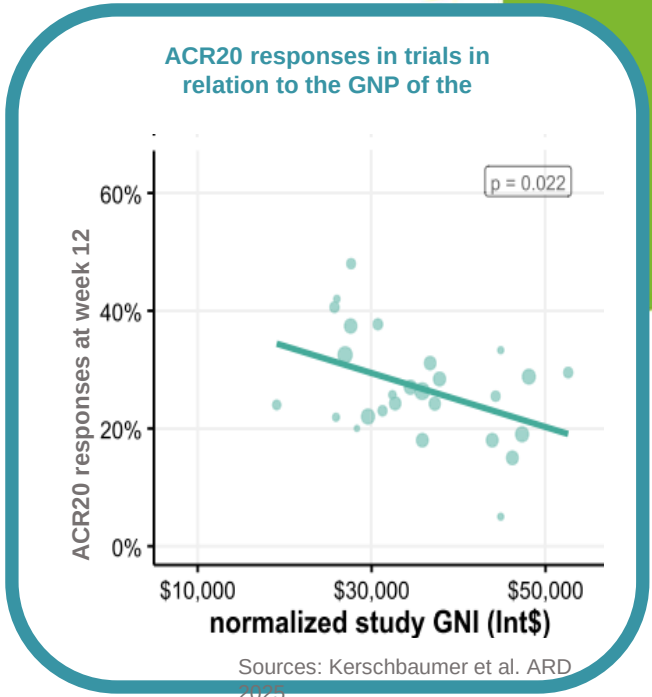
The Objectives

*"Leverage European Excellence –
Rebuild Europe's attractiveness for clinical research"*

Specific Objective 2: Integrate fragmented health R&I efforts bringing together health industry sectors and other stakeholders, focussing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users



Sources: Kerschbaumer et al. ARD 2025

Obj. 1: To overcome regulatory fragmentation and to implement streamlined operational governance

Obj. 2: To tackle limited and fragmented site capacity and training gaps

Obj. 3: To integrate data & privacy silos

Obj. 4: To reduce patient recruitment bottlenecks (capacity building and network integration)

Obj. 5: To leverage Europe´s excellence and quality for a large patient community

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Towards an Integrated European Trial Ecosystem

WP2 – Workforce and site capacity
- Clinical Trials Academy, twinning of experienced and emerging sites.

WP3 – Recruitment and patient engagement
- EU trial-finder platform, inclusion campaigns, patient advisory boards.
- Make participation more accessible, inclusive, and aligned with patient priorities.

WP1 – Governance and regulatory alignment
- Streamline regulatory interactions,
- Harmonise and simplify multi-country ethical and regulatory procedures.

WP4 – Data interoperability
- Build interoperable infrastructures for data integration and secure sharing.
- Leverage analytics to drive evidence-based, connected health solutions.

WP7 – Project Management, Ethics, Dissemination, Communication & Sustainability
- Ensure transparent governance, ethical compliance, and efficient coordination.
- Promote dissemination, stakeholder engagement, and long-term project sustainability.

WP6 – Innovative methodologies and digital enablement
- Hybrid immunology pilots, adaptive design workshops.

WP5 – Evaluation and observatory
- European KPI dashboard, learning cycles.

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Why now?

- EUROPE is at a crossroads – clinical research capacity eroding while innovation accelerates globally.
- New EU Clinical Trials Regulation (CTR) and EHDS create unprecedented momentum for harmonisation.
- Digital tools and AI offer practical solutions for efficiency and equity.
- Public trust and patient engagement demand transparent, accessible research.
- Without coordinated action now, Europe risks permanent loss of clinical trial leadership.

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Why IHI?

Topic 2: Boosting innovation through better integration of fragmented health R&I efforts

- **Public-Private Partnership Model:** Bridges academia, industry, regulators, patients.
- **Alignment with EU Health Priorities:** Supports innovation ecosystems under Horizon Europe.
- **Enables co-investment** (EC + industry in-kind ~ €30 M total).
- **Ensures impactful, co-owned solutions** with shared responsibility and scalability.
- IHI is the only framework capable of delivering **pan-European system change**.

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Outcomes and Impact

Patients & their supporters

Researchers & Scientific community

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Healthcare Systems & Providers

Small & Medium-sized Enterprises (SMEs)

Regulators & Ethics Bodies

Medical Industry

Society & EEA

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Expertise and resources

CURRENTLY ENVISAGED PARTNERS

- Trial network models: Scandinavian network integration model
- Recruitment effectifiers: ENTRI (Site engagement); Preferrix (Community engagement); EULAR (Patient engagement)
- National and European Regulators and Ethical Committees
- Major industry partners with interest in quality data and low placebo response in their trials

ADDITIONAL PROJECT PARTNERS TO BE ENGAGED

- Additional Patient Advocacy Groups (on top of EULAR-PARE)
- Economic scientists/experts (macroeconomic perspective)
- Additional industry partners (with interest in conducting trials within the developed framework)
- Software developers (creating platforms and front-ends)
- CROs

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