

IHI Call Days | Call 12



ENGAGE2USE: Collaborative Action
for Responsive Engagement and
Enabling People-Centred Innovation

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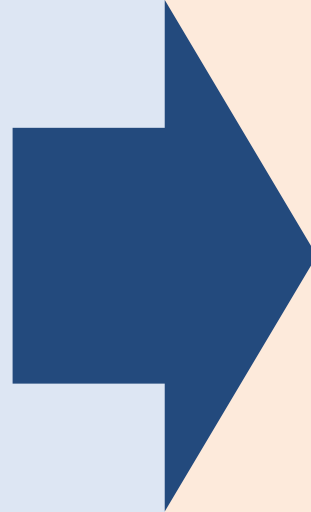
[Link to the IHI brokerage platform](#)





Challenges

- Limited patient access to health data and low digital and health literacy
- Lack of personalisation due to of low and diverse patient engagement in healthcare innovation
- Regulatory and system-level barriers to the implementation and scaling of safe, integrated digital health solutions



VISION

To lead the shift toward people-centred chronic disease management by empowering patients with digital tools that enhance diagnosis, support self-care, and enable truly integrated care across Europe.

Challenges and Objectives

Key Challenges:

- Fragmented healthcare and slow uptake of digital innovations
- Low patient engagement and limited digital/health literacy, especially among vulnerable groups
- Limited evidence on how to implement digital tool in real-world care
- Gaps between regulatory frameworks (EU/FDA) and uneven data interoperability

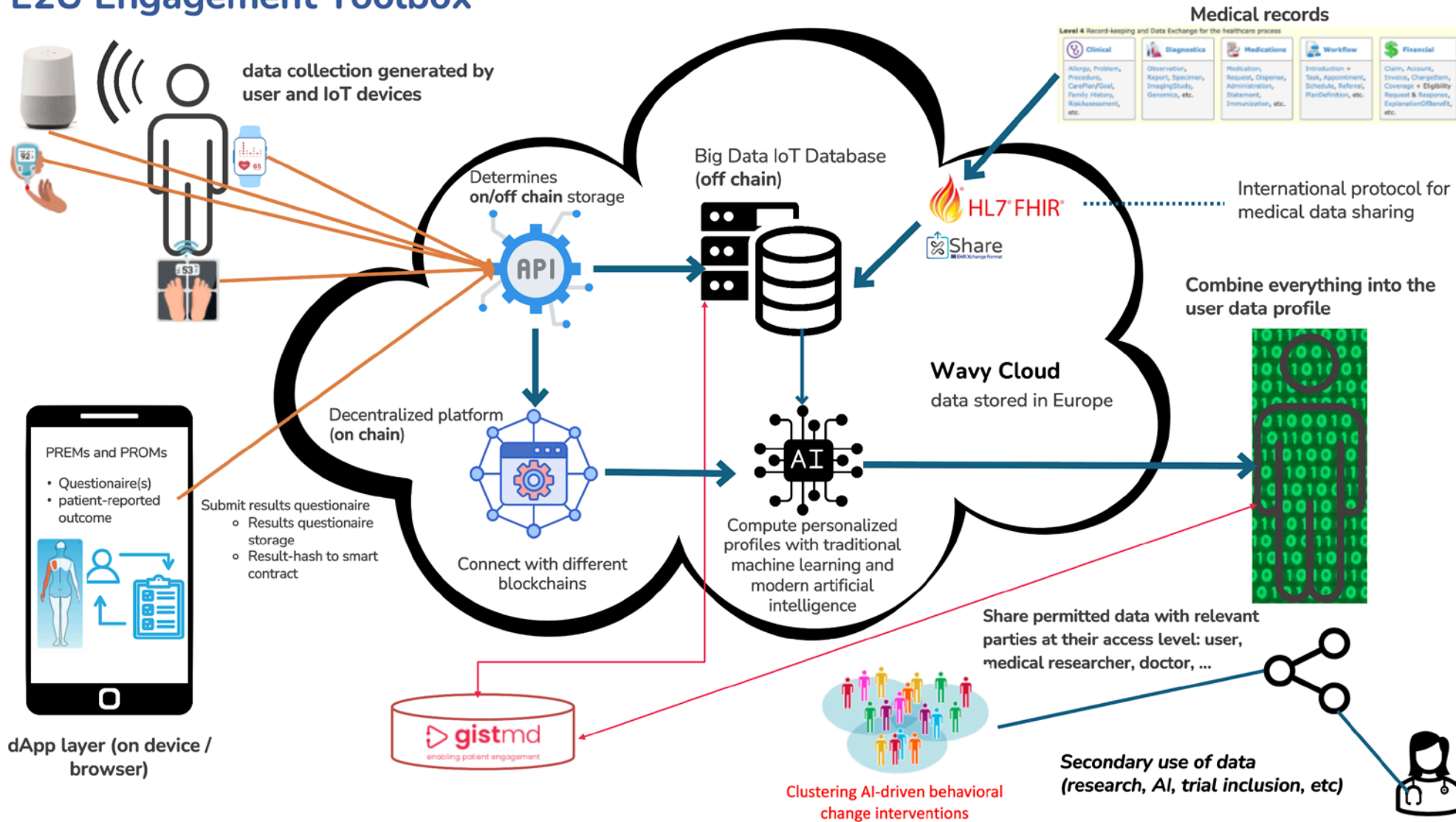
Our Objectives:

- Designing and validating **E2U's unique innovation for Care Matrix**: will create a unique classification tool of patients' preferred level of engagement with healthcare innovations according to the different stages of their care continuum, fostering integrated care
- **Framework for PDURS EU implementation and application in HTA setting**: Policy Labs develop innovative public policies by engaging citizens, vulnerable patients, companies, and the public sector through a user-centered design-driven approach (Align EU and FDA regulatory approaches for trustworthy digital therapeutics)
- **E2U Engagement Toolbox** to support innovators with engagement of patients during the innovation process, co-creation with stakeholders, stratifies trial participants and collects patients' needs during the development
- Bring **12 (digital) health innovations** across CVD, Respiratory, Diabetes and Obesity to a higher TRL level
- Implement and evaluate (digital) health innovations across EU (**E2U Engagement labs**)
- Evaluating **real-world impact and value creation** of digital health innovations across the quintuple aim
- Ensuring robust data governance, ethical compliance, and privacy-preserving analytics for E2U's digital health innovations
- Engaging key stakeholders and to facilitate adoption, define policy alignment, and ensure that E2U's outcomes inform European healthcare strategies
- Viable business strategy and sustainability to accelerate the innovations

Our Approach

- **Understand Patient Engagement** – Identify how people engage with innovations to design and tailor solutions, ensuring inclusivity from the start across the care continuum.
- **Shape Policy and Regulations** – develop EU-FDA guidance with regulators, HTA bodies and policy makers to enable safe, scalable adoption of digital health tools.
- **Build Digital Foundations** – Develop an open, secure and interoperable toolbox that supports explainable AI, data sharing and personalised engagement
- **Test in Real-World Labs** – Seven engagement and innovation labs across Europe co-create and pilot digital solutions for chronic respiratory and cardio-metabolic conditions with diverse and vulnerable populations.
- **Evaluate and Scale** – Measure social and economic impact and define scalable models for sustainable people-centered care.

E2U Engagement Toolbox



Outcomes and Impact

Expected Outcomes:

- Validated, people-centered digital tools integrated into hybrid care models
- Improved self-management and adherence among patients
- Enhanced health and digital literacy
- Clear models for regulatory and data alignment across Europe

Expected Impacts:

- Citizens empowered to manage their own health
- Digital health adoption that is equitable and evidence-based
- Stronger partnership among patients, clinicians and innovators.
- Demonstrated scalability and sustainability of integrated care.

Expertise and Resources

Our strength

- Over 30 Partners from 16 countries:
 - Leading research universities, regulatory, and implementation science leaders
 - Over 10 industry partners (from COCIR, efpia, MedTech Europe)
 - Strong collaboration with patient organisations: European level (3) and national networks (9)
 - European leaders like DIA, HL7 Europe, CBG

Our resources

- Interoperable AI-driven toolbox
- Seven real-world labs for testing innovations in CVD, Respiratory, Diabetes and Obesity
- Integrated evaluation for clinical, economic and social impact.

Is your project suitable for IHI?

The E2U Public-Private partnership will enable:

- Private partners to contribute the evidence base, behavioral insights and implementation science capabilities needed to implement, evaluate and scale people-centered innovations.
- Private partners, particularly from the pharma, med-tech and digital health companies to bring cutting edge tools and technologies into the E2U engagement and innovation labs for real-world piloting and validation.

What are we looking for?

Pharmaceutical who wish to test and demonstrate innovative digital solutions for respiratory, CVD, diabetes and obesity within E2U's platform and unique real-world labs network.

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