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The first European Digital HTA framework cocreated by all stakeholders along the value chain

Background

Health systems worldwide face workforce shortages, aging populations, and financial pressures, challenges intensified by effectively integrated, COVID-19. When Digital Technologies (DHTs) can enhance sustainability and care quality, but regulatory and systemic barriers often hinder their adoption and reimbursement. A new, innovative, digital Health Technology Assessment (HTA) framework dedicated to DHTs could harmonise assesment criteria and support efficient integration of DHTs from policy making to clinicians and patienst level.

Aim

The EDiHTA project aims to develop a Health Technology Assessment (HTA) framework for DHTs that combines existing assessment methods with innovative approaches to support decision-making at all levels. The framework will be digital, flexible, and adaptable, allowing standardised or customised assessments based on DHT type, lifecycle stage, and decision-making context at the macro (policy), meso (management/providers), and micro (clinicians/patients) levels.

Results & Key Findings

The Patient Advisory Group (PAG), established by EPF in 2024, unites 15 patient experts and representatives selected through an open call by EPF. Members bring together a diverse mix of disease areas, regions, age groups, genders, and levels of digital health

engagement ensuring a broad range of patient perspectives. Geographic Representation Technology Expertise UK **Mobile Health Apps** AI Malta Greece **Digital Devices** Telemedicine Italy Slovakia **Gender Distribution** Czech Republic 1 Spain **Finland** Germany women **Estonia** = balanced patient perspectives **Disease Area** Non-Alcoholic Steatohepatitis Cardiovascular (NASH) Inflammatory Bowel Diabetes Disease Hereditary TO TO Migraine Angioedema

Respiratory

Diseases

Mental Health

Kidney disease

PAG's contributions to EDiHTA

Three Focus Group discussions were conducted with the support of the European Patients' Forum and Università Cattolica del Sacro Cuore (UCSC) to explore patients' perspectives on emerging DHTs. The discussions focused on the use of artificial intelligence healthcare, telemedicine services, mobile health applications, and digital medical devices. The direct contributions of PAG members played an important role in shaping EDiHTA Deliverable "Health Decision-Makers' 3.3, Needs and Requirements."

Engaging the Patient Community

EPF engaged its broad patient community through multiple participatory activities:

- Podcast Series (3 episodes), launched by EPF to deepen conversations around DHTs.
- EPF Members' Circle series, a platform for dialogue and knowledge exchange across the patient community in Europe.

DHTs: What Patients Say?

1. Putting Patients at the Heart of Digital Health Design

- Early and meaningful patient involvement is essential in designing and developing DHTs.
- Clear, understandable information enables patients to use technologies confidently and independently.
- Participation of patient organisations in regulatory and HTA processes ensures that the patient perspective is embedded in technology evaluation, enhancing legitimacy, transparency, and ethical standards.

2. Trusted Guidance Matters

- Patients trust and adopt tools recommended by healthcare professionals.
- Personalised guidance helps patients feel confident.

their health data is collected, stored, and used.

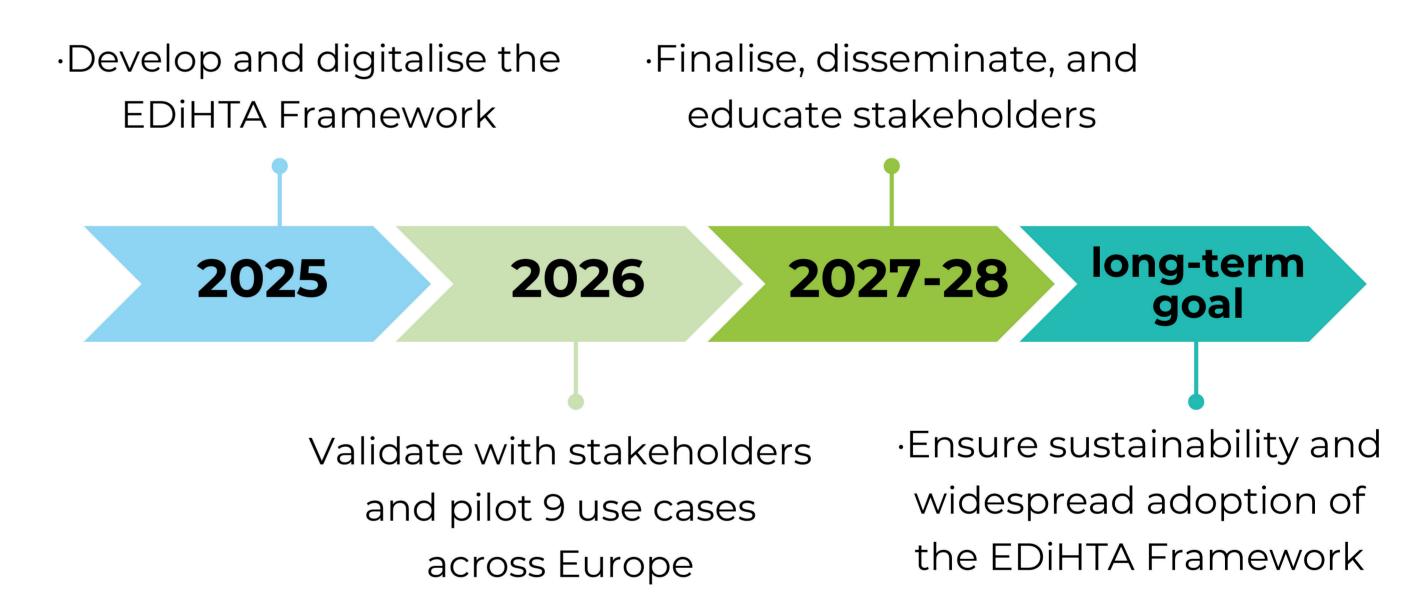
 Co-design with patients and clinicians ensures tools fit real-life care.

- 3. Empowering Patients through Data Transparency and Ethics Patients prioritise transparency, choice, and control over how
- Robust cybersecurity and ethical digital practices are fundamental to building trust.
- Patients raised ethical considerations about recognition or compensation for contributions of their data toward new tools or treatments.

4. Bridging Gaps: Overcoming barriers to Digital Health Access

- Low digital and health literacy, high costs, limited access to devices, and infrastructure gaps create barriers to DHT adoption.
- Device fatigue and fragmentation of health systems challenge patient engagement.
- Greater transparency in decision-making by regulatory and HTA bodies is needed.

From Design to Deployment: **EDiHTA Roadmap for DHTs**



Join us in the co-creation phase!

1. Stakeholder Open Evaluation phase

How? Participate via our online survey When? March 2026

Who? Everyone is welcome

Your input will directly shape the EDiHTA Framework!

2. Open Pilot phase

How? Join the piloting phase through online meetings

When? September 2026 – April 2027

Who? Participants selected based on criteria shared in early 2026

Be part of testing and shaping EDiHTA framework in real-time!

Stakeholders



UNIVERSITÀ CATTOLICA del Sacro Cuore





Cancer

Rheumatic Diseases





































