EDiHTA: Patient's perspective in the evaluation process of Digital Health Technologies

Alessandra Pernice | Emmanouil Tsiasiotis

EDiHTA

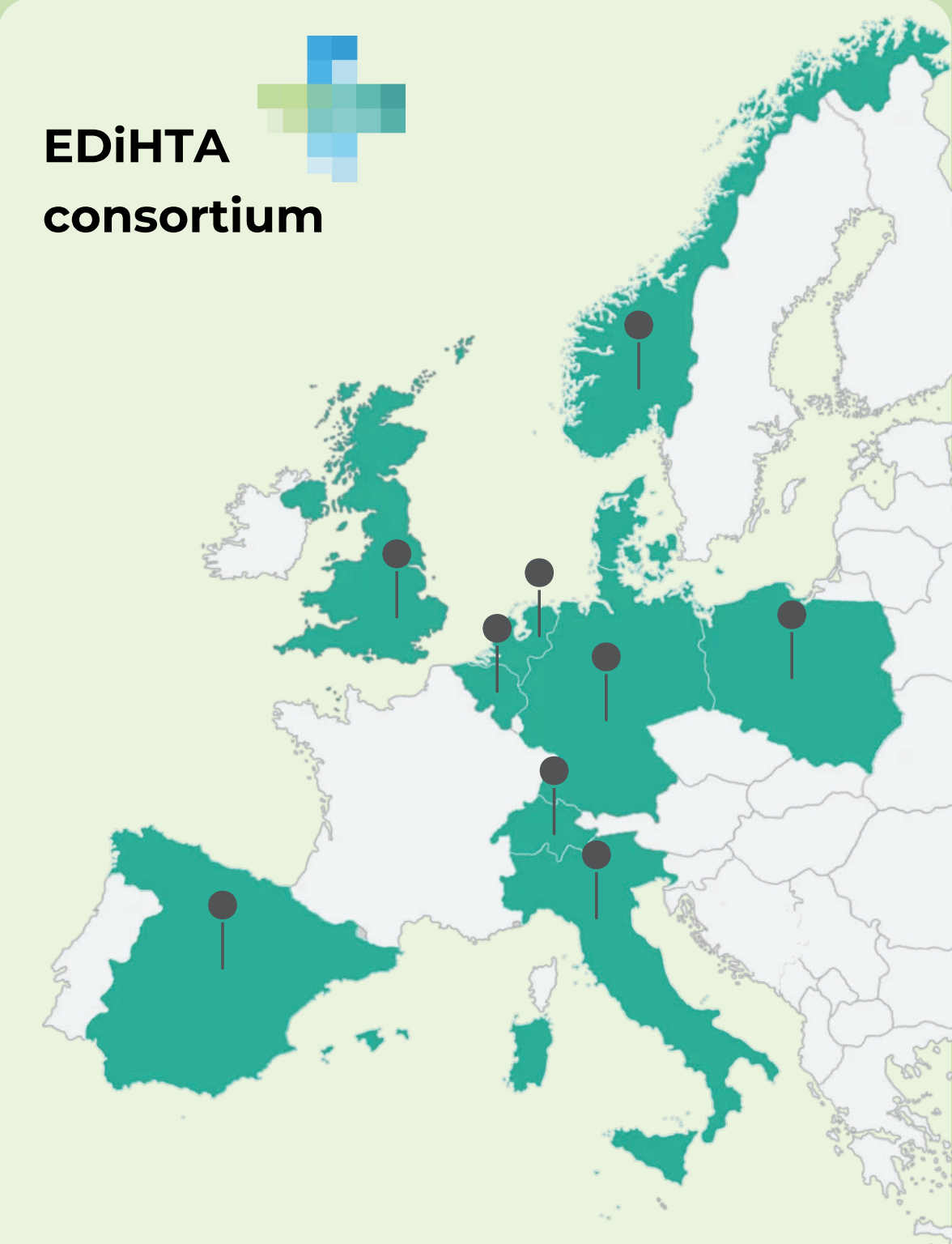# THE EDiHTA PROJECT

DURATION 01.01.2024 – 31.12.2027

HORIZON-HLTH-2023-IND

COORDINATOR Università Cattolica del Sacro Cuore, Italy

BUDGET 8.4 million euro

Background

Health systems globally grapple with shortages in healthcare staff, ageing demographics, and financial constraints, amplified by the COVID-19 pandemic. Digital Health Technologies (DHTs) when integrated adequately in health systems can support the workforce increasing sustainability with quality solutions. Regulatory aspects along with unprepared systems can complicate market access and reimbursement for DHTs, hindering innovation. A new, innovative, digital Health Technology Assessment (HTA) framework dedicated to DHT should harmonise assessment criteria and support efficient integration of DHTs from policy making to clinicians and patients level.
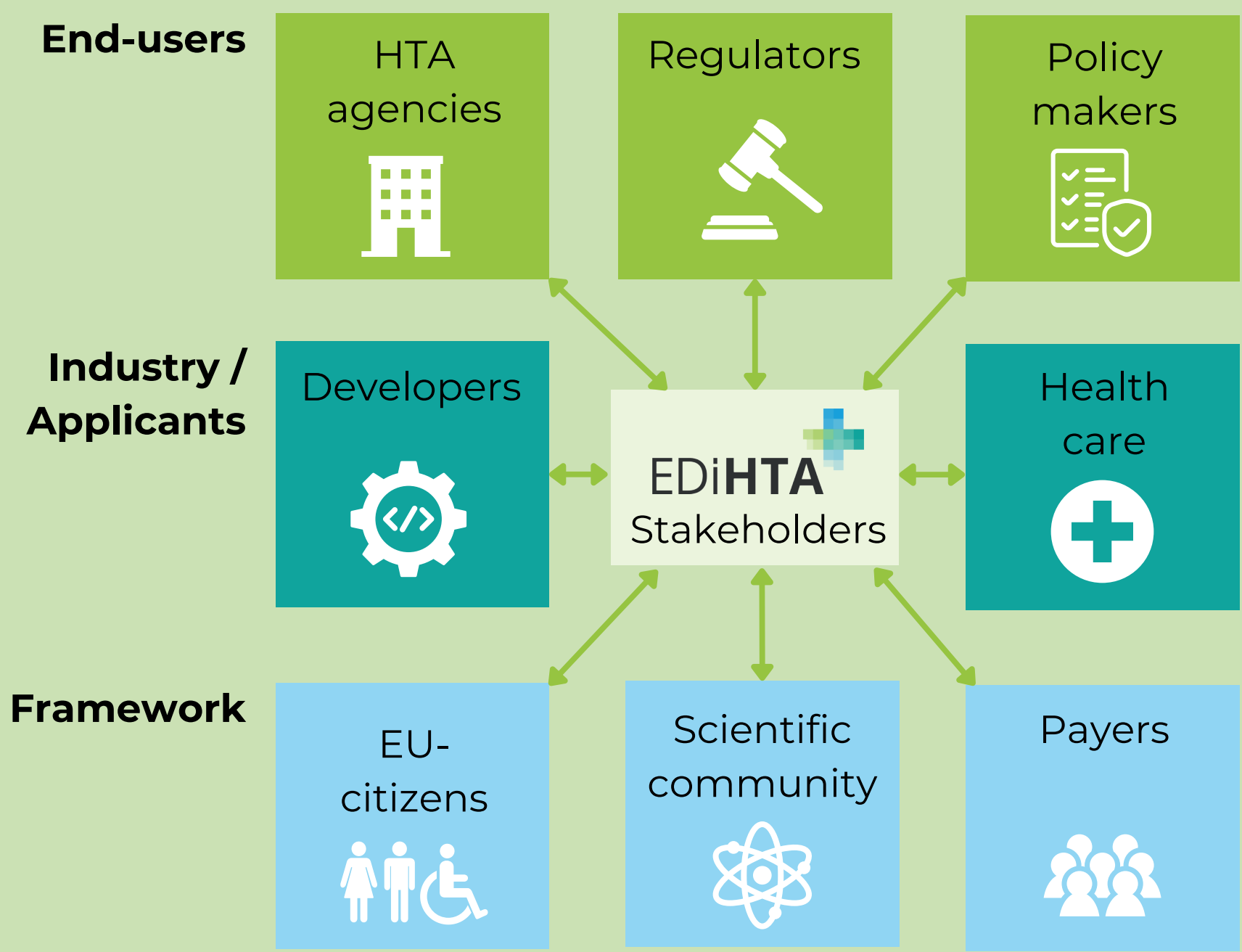
EDiHTA consortium

A joint effort of 16 European partners from 10 countries, including **clinical partners**, **regulatory bodies**, **HTA agencies** and links to technology developers and payers.

Aim

The overall objective of the EDiHTA project is to provide a Health Technology Assessment (HTA) framework for Digital Health Technologies (DHTs) that integrates existing assessment domains and methods with new approaches, in order to support decision-making at all levels. The HTA framework will be innovative, digital, and flexible, allowing for standardized and customized assessments based on the type and lifecycle stage of the DHT and the decision-making process at the macro (policy), meso (management providers), and micro (clinicians and patients) levels. A key aspect of the project is the development of a comprehensive framework that integrates feedback from various system levels, including the perspective of patients and patient advocacy groups (PAGs). By incorporating their experiences and needs, the framework will ensure that technologies are aligned with real-world challenges and meet the concrete needs of those who use them.

Stakeholders

End-users

- HTA agencies
- Regulators
- Policy makers

Industry / Applicants

- Developers
- EDiHTA Stakeholders
- Health care

Framework

- EU-citizens
- Scientific community
- Payers

Results

Literature review

Patient satisfaction: user friendliness, improve treatment efficiency, burden relief for caregivers;
Patient engagement: patients involvement in all phases of technology (involvement with developers), from development to real life use and ongoing feedback on the interaction;
Patient empowerment: understanding the use of the technology, literacy level and training;
Patient support: reducing loneliness and social isolation ;
Patient safety: clinical safety (preventing medical errors) and technical safety (data protection and support to clinical decision-making);

Focus groups

Adoption, Training, and Support for DHTs:
- Adoption and Training: rapid DHT adoption requires continuous training for healthcare professionals to improve service quality and digital integration;
- Healthcare Professionals and Caregiver Guidance: a crucial role in advising patients on the safest and most suitable DHTs, promoting shared decision-making;
- Personalised Patient Support: tailored assistance helps address technology-related challenges, adapting to different levels of digital literacy;
- Empowering Patients: education, simulations, and early involvement in DHT development increase patient confidence and adherence;

Data Barriers and Transparency
- Data Control and Transparency: patients need clear information on who accesses their data and how it's used to build trust;
- Digital Education: support for seniors and other groups facilitates technology adoption;
- Data Sharing: Addressing ethical issues promotes secure and transparent data-sharing practices;

Security and Trust in Digital Technologies
- Cybersecurity: strong data protection is essential, especially for sensitive devices;
- Developer Responsibility: developers must ensure reliable, high-quality DHTs, drawing on patient feedback;

Medical Device Safety
- Enhanced Safety: strengthening safety measures ensures effectiveness, especially for those with mental health conditions;
- Trust in Regulatory Authorities: building trust in approval processes supports DHT acceptance;

GDPR and Data Use
- Regulations and Transparency: reviewing GDPR limitations can improve data management and reduce bias;
- Control and Compensation: provide patients with greater control over their data and explore the possibility of compensating them for its use.

Conclusions

The findings highlight the importance of developing a flexible and adaptable framework for the assessment of Digital Health Technologies (DHTs), placing patients at the center of decision-making processes. This analysis, combined with the collected inputs, will lead to the design of the EDiHTA framework, ensuring it addresses the real needs of patients and the stakeholders involved.
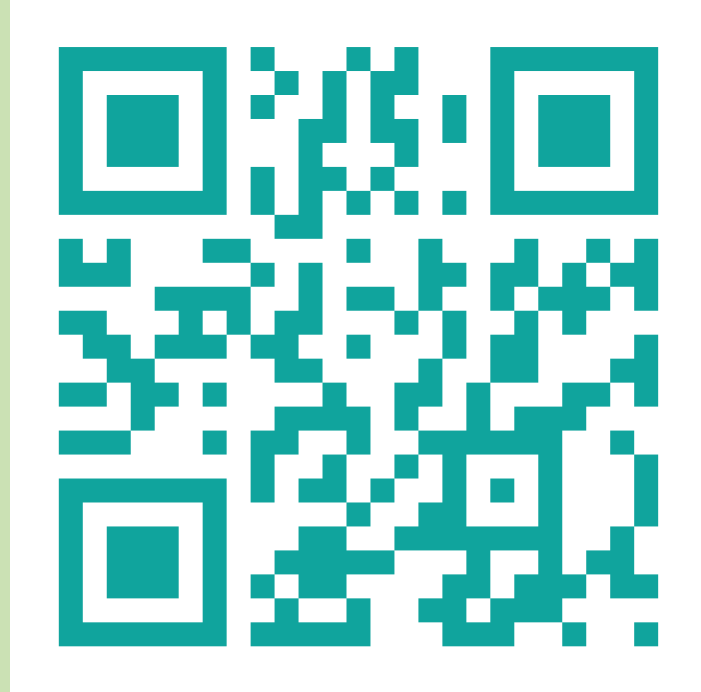
edihta-project.eu

> Uniting experts across sectors, our consortium is dedicated to shaping the future of the European healthcare landscape with the first European Digital Health Technology Assessment Framework.

Prof. Americo Cicchetti
Full professor, General Director of Programming of the Ministry of Health Italy
EDiHTA project coordinator

Università Cattolica del Sacro Cuore · Radboud umc university medical center · OUH Odense Universitetshospital · IDIBAPS · UNIVERSITÄTSKLINIKUM FRANKFURT GOETHE-UNIVERSITÄT · Clínic Barcelona · Universitat de Barcelona · agenas. · AGENZIA NAZIONALE PER I SERVIZI SANITARI REGIONALI · Salut/ Agència de Qualitat i Avaluació Sanitàries de Catalunya · Norwegian Centre for E-health Research · DNV · EHMA European Health Management Association · eit Health · Co-funded by the European Union · EPF European Patients Forum · Health Policy Institute · accelopment · NICE National Institute for Health and Care Excellence

EDiHTA-EU-project · @EDiHTAProject · info@edihta-project.eu

©accelopment Schweiz AG