

European Framework for Advanced Medical Technology Evaluation and Follow-up

EU4MEDTECH is a transformative **Horizon Europe** project dedicated to enhancing regulatory pathways for high-risk and innovative medical devices (MDs) and in-vitro diagnostic medical devices (IVDs) across Europe. Focused on improving evaluation and lifecycle management, the project aims to ensure safer and more efficient patient care. Bringing together 14 partners from 10 European countries, EU4MEDTECH is shaping the future of medical technology.

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PROJECT PARTNERS



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EU4MEDTECH

PROJECT PHASES

01 PRE-STUDY

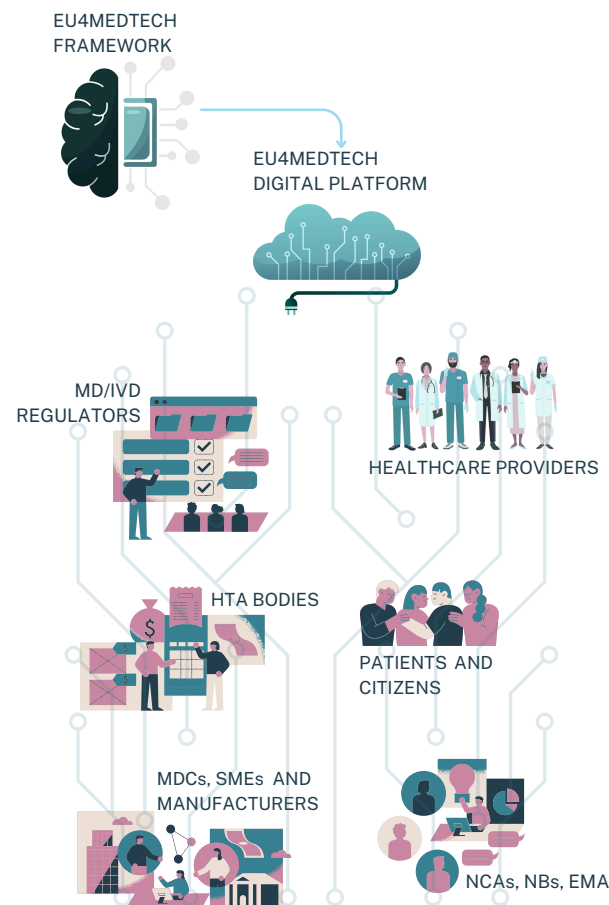
Establishing the EU4MEDTECH framework and platform by assessing regulatory requirements, stakeholder needs, and evaluation methodologies.

02 DEVELOPMENT

Developing the EU4MEDTECH framework, refining Common Specifications, and building a digital platform for MDR/IVDR compliance.

03 TESTING AND EVALUATION

Validating the framework and digital platform through three Use Cases and a Proof-of-Concept study for optimized clinical and performance evaluation.



EU4MEDTECH will develop a comprehensive framework and a digital platform to support the integration of innovative solutions into healthcare systems.

By bringing together academia, industry, healthcare providers, and regulatory bodies, the project bridges the gap between innovation and practical implementation.

MAIN RESULTS

EU4MEDTECH Framework

A comprehensive framework designed to standardize the generation and evaluation of clinical and performance evidence for high-risk MDs and IVDs across pre-market and post-market stages.

EU4MEDTECH Digital Platform

A cloud-based platform operationalizing the EU4MEDTECH Framework. It features a regulatory communication channel, global regulatory search functionality, a user training module, and a data repository to streamline medical device evaluation processes.

Validated Use Cases

Application and testing of the framework in three distinct use cases: Class III and implantable devices, Class C/D in vitro diagnostics, Software-based medical devices.

Recommendations for Common Specifications

Development of new guidelines and specifications to enhance the regulatory environment, fostering innovation while maintaining safety and compliance.