



**Acronym** REALM

**Full title** Real-world-data Enabled Assessment for health regulatory decision-making

**Programme** Horizon EUROPE/ HORIZON-HLTH-2022-TOOL-11

**Contract number** 101095435

**Summary** The overall aim of the REALM project is to create a collaborative framework for regulatory authorities, application developers, healthcare professionals and policy officers to co-create and evaluate software for medical and healthcare use. We propose to create an inclusive platform leading to a transparent ecosystem for the evaluation and certification of software in healthcare where both the developers and the regulatory (and Health Technology Assessment) bodies have access to a standardised set of technology stacks and data.

This will be achieved by first mapping and analysing regulations, legislative efforts and guidelines from the EU, national bodies and around the world on software in healthcare practice. These will guide the roadmap towards building an inclusive, fair and multi-stakeholder ecosystem. The scaffold for an integrated architecture will be developed in collaboration with DARWIN, based on standardised data models and optimised data-driven methodologies for the effective use of real-world data (RWD) in healthcare regulatory practice.

The architecture will consist of four components: two technological infrastructures, a living lab and a post-marketing surveillance module. i) a federated cloud-based data resources catalogue will be established, to bring together currently available RWD data and synthetic data to facilitate the data needs of the platform. ii) Regulatory Toolbox will be established to bring together standardized tools to train, test, evaluate and monitor medical/healthcare software. iii) Living lab environment for piloting medical/healthcare software technology assessment taking into account human-software interactions as part of the system. iv) Post-marketing surveillance with RWD to ensure quality standards of the certified software in practice. Finally, building on the proposed architecture, five real Medical Device Software (MDSW) projects are going to be implemented across three countries (Netherlands, Belgium and Greece).

**Duration** Four years (01/01/2023 - 31/12/2026)

**Project funding** €6,659,650.00

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- Partners**
- Belgium
- COMUNICARE – Comunicare Solutions
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  - VITO – Vlaamse Instelling Voor Technologisch Onderzoek N.V.
  - VPH INSTIT – Virtual Physiological Human Institute for Integrative Biomed Research Vzw
  - UANTWERPEN – Universiteit Antwerpen
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**Website** [www.realm-ai.eu](http://www.realm-ai.eu)