Press Release

New EU Research Project REALM

Multi-Stakeholder Ecosystem for the Co-creation and Evaluation of Medical Device Software

On the 19th-20th January 2023, the Kick-off meeting of the interdisciplinary consortium of the European research project REALM, takes place in Maastricht. The consortium is led by Distinguished Professor Michel Dumontier from Maastricht University and is composed of 13 European partners and two associated partners. Together they will develop a collaborative framework through which regulatory authorities, software developers, healthcare professionals and policy offers can jointly create and evaluate innovative medical device software – for the direct benefit of patients and healthcare practitioners.

The adoption of software in healthcare, mostly used in hospitals and research organisations, is rapidly changing how diagnostic, therapeutic and prognostic procedures are developed by researchers, delivered by healthcare providers, and ultimately experienced by patients. Innovative software solutions have the potential to strengthen healthcare and clinical practice through earlier or more accurate diagnoses, decision support for practitioners or personalised treatment plans. The transition to this reality of software-assisted healthcare, combined with the changing European regulatory landscape, however, comes with new challenges. Especially regulators and health technology assessment agencies are faced with new questions. Therefore, newly proposed software solutions must be evaluated critically as the changes that will come with their certification and integration into daily practices will have major impacts on health care provision, but also the society and economy as a whole. Regrettably, the current evaluation and certification practice of medical device software solutions is inadequate to address the newly arising challenges.

For this reason, the new research project REALM (Real-world-data Enabled Assessment for heaLth regulatory decision-Making), a collaboration of 15 partners from six European countries, has been established. The consortium sets out to develop an innovative and inclusive platform that leads to a transparent ecosystem for the evaluation and certification of software in healthcare where developers as well as regulatory and health technology assessment bodies have access to a standardised set of technology stack and data.

Pioneering tools and standards for thorough and speedy certification of novel healthcare software

“If the EU wants to keep up with medical software innovations, standardised data and analysis platforms as well as good practice sharing as part of the regulatory practice will become an essential prerequisite. To this extent, REALM will contribute to the provision of methodologies, algorithms, tools and reference implementations for the development and

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adoption of credible and ethically sound medical device software. In addition, we want to remove barriers for the adoption and acceptance of real-world data-driven and artificial intelligence/machine learning-based evaluation, certification, verification and validation of healthcare software. Also important as part of our research is to reduce inequalities in the regulatory field by creating outreach and education channels that are sustainable beyond the project", says Michel Dumontier, Distinguished Professor of Data Science at Maastricht University and coordinator of the REALM consortium.

To reach these ambitious goals, the REALM team will first map and analyse existing regulations and legislative guidelines on software in healthcare practice. This will inform a roadmap towards building an inclusive multi-stakeholder ecosystem guided by the FAIR Guiding Principles which requires data to be findable, accessible, interoperable and reusable. In collaboration with DARWIN, the EU Data Analysis and Real-World Interrogation Network, the integrated architecture will feature two technological infrastructures, a living lab and a post-marketing surveillance module. This will include a federated cloud-based data resources catalogue to compile available real-world data and synthetic data to facilitate the data needs of the platform. A regulatory Toolbox will collate standardised tools to train, test, evaluate and monitor healthcare software. The living lab environment for piloting medical software technology assessments will allow for human-software interactions as part of the system. The post-marketing surveillance with real-world data will ensure the necessary quality standards of the certified software in practice.

"Central to the project will be five case studies, undertaken in The Netherlands, Belgium and Greece, that will validate and improve the REALM platform based on medical device software used to address currently unmet clinical needs, ranging from blood glucose control in patients in intensive care units to testing Pharmacogenomics passports in clinical practice", adds Gökhan Ertaylan, Research Lead - Precision Health at VITO (Vlaamse Instelling Voor Technologisch Onderzoek) , Belgium, and Co-coordinator of REALM.

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Project Key Facts

Full Name: REALM – Real-world-data Enabled Assessment for heaLth regulatory decision-Making
Start Date: 1st January 2023
Duration: 48 months (until 31st December 2026)
Budget: €6,659,650.00
Coordinator: Maastricht University, The Netherlands
Website: www.realm-ai.eu

Project Partners

- Comunicare Solutions, Belgium
- European Research and Project Office GmbH, Germany
- Exus Software Monoprosopi Etairia Periorismenis Evthinis, Greece
- Metamind Innovations Ike, Greece
- The Chancellor, Masters and Scholars of the University of Oxford, United Kingdom
- Traqbeat Technologies Idiotiki Kefa, Greece
- Uczelnia Lazarskiego, Poland
- Université de Liège, Belgium
- Universiteit Antwerpen, Belgium
- Maastricht University, The Netherlands
- University of Bristol, United Kingdom
- Uniwersytet Warszawski, Poland
- Virtual Physiological Human Institute for Integrative Biomedical Research Vzw, Belgium
- VITO (Vlaamse Instelling Voor Technologisch Onderzoek), Belgium
- Yaghma B.V., The Netherlands

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