REALM – innovative solutions for the creation and evaluation of AI medical device software.

Title: Advancing Certification and Evaluation of Medical Device Software in the EU using OMOP.

Background: In the landscape of healthcare, the increasing complexity and autonomy of Medical Device Software (MDS) present significant challenges in their certification and post-market monitoring, particularly in adapting to real-world healthcare settings. To address these challenges, the REALM project, also known as Real-world-data enabled assessment for health regulatory decision-making, aims to provide a robust testing infrastructure for the evaluation and certification of MDS in the European healthcare industry. By emphasizing transparency through the use of OMOP (Observational Medical Outcomes Partnership) databases and extensions, REALM seeks to offer stakeholders and regulatory bodies detailed and transparent insights into the performance of AI models embedded in MDS, crucial for ensuring trust and reliability in medical software solutions.

REALM is a significant collaborative effort involving 15 partners across Europe (Figure 1). Within this consortium, five partners act as demonstrators, providing AI models for evaluation of the REALM capabilities to generate relevant testing dataset and evaluate how AI models performed. Given the diversity of data types required by the demonstrators (and future AI models) REALM heavily rely on the OMOP CDM and Extensions (R-CDM - Park et al., 2022 & G-CDM - Shin et al., 2019) to harmonize source data (Figure 2) from the REALM data catalogue and provide a unique way to query and generate test datasets. Following this approach, REALM also plans to incorporate data from the embedded synthetic data generator and digital human twin into its evaluation framework. By integrating these additional resources, REALM aims to further enhance the diversity and richness of its testing datasets, providing a more comprehensive assessment of AI model performance across various healthcare scenarios.

Conclusion: REALM’s integration of diverse data sources using OMOP CDM together with the REALM’s rigorous framework provide regulatory bodies with a powerful sandbox environment for a transparent and precise assessment of medical AIs.