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.

Figure1: REALM Partners across Europe.

Figure2: REALM interoperability vision & harmonization plan.
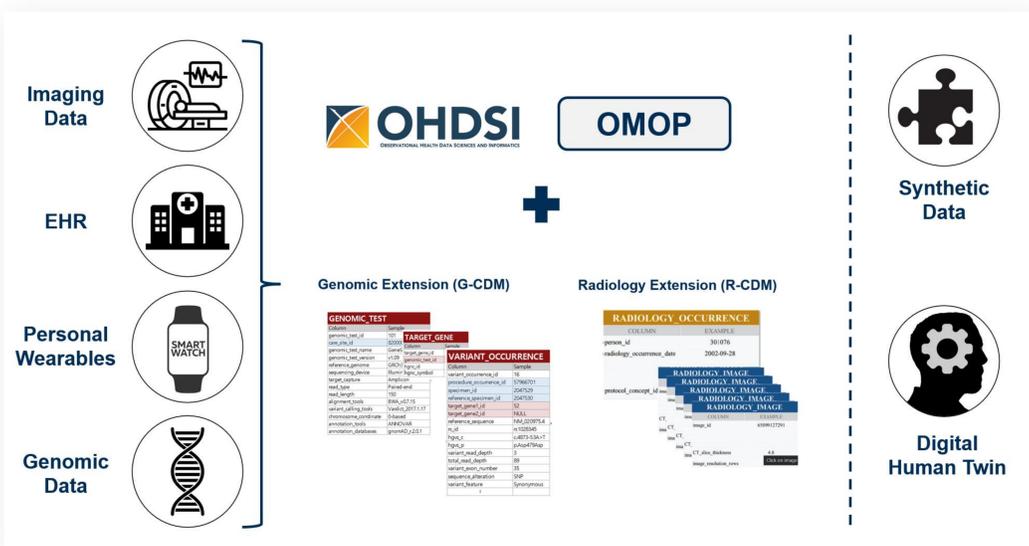
REALM is a significant collaborative effort involving 15 partners across Europe (*Figure 1*). Within this consortium, five partners act as **demonstrators**, providing **AI** models for evaluation of the REALM capabilities to generate relevant testing dataset and evaluate how **AI** models performed. 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.

REALM
EU Project n°101095435

Frédéric Jung[1], Chang Sun[2], Mahmoud Ibrahim[2], Gökhan Ertaylan[1]

1) VITO, Vlaamse Instelling voor Technologisch Onderzoek, Mol, Belgium

2) Institute of Data Science, Maastricht University, Maastricht, the Netherlands