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EUROPEAN RESEARCH AND PROJECT OFFICE GMBH

Factsheet

REDDIE

FULL TITLE REDDIE – Real-world evidence for decisions in diabetes

PROGRAMME HORIZON-HLTH-2022-TOOL-11

CONTRACT NUMBER 101095556

ABSTRACT Randomised controlled trials are the cornerstone of evidence-based medicine. However, the digitisation of real-world data (RWD) including data from devices, wearables, and electronic health records in large national registries provides opportunities to demonstrate the efficacy and safety of innovative technologies including drugs, devices, diagnostics, and digital health. These data are particularly relevant to long-term conditions such as diabetes mellitus, where drugs, lifestyle interventions, and digital technologies often work together. To better utilise RWD in diabetes for regulatory decision-making, the development of standards, guidance, and an assessment of the efficacy-to-effectiveness gap is needed. REDDIE (Real-World Evidence for Decisions in Diabetes) aims to explore how RWD can complement RCTs to improve the efficacy, safety, and value for money of technologies to prevent and treat diabetes. The overall aim of REDDIE is to support the use of RWD in diabetes and health-related research, which will maximise Europe's scientific expertise and know-how to benefit people with diabetes, resulting in safer, more efficient, and cost-effective interventions. We thus aim to engage with stakeholders such as regulatory and HTA authorities and co-develop evidentiary standards for the collection, assessment, and acceptability of RWD. We will then develop and validate state-of-the-art modelling techniques using synthetic data derived from large national registries to better assess the outcomes of interventions using RWD. We will use data from four large national registries to elucidate the gap between outcomes in RCTs and RWD studies and understand the factors that affect this gap. Finally, we will test the ability of machine learning to facilitate the better use of RWD. REDDIE will generate standards for RWD use for evaluating medicines and other interventions by regulatory authorities and HTA bodies.

DURATION 48 months (01/01/2023 – 31/12/2026)

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