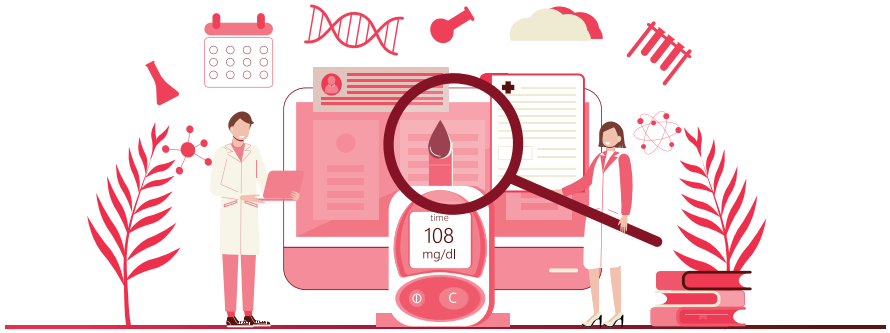
REDDIE

Better care for people living with diabetes through real-world data



About REDDIE

Randomised controlled trials (RCT) 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 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. We aim to leverage RWD to complement RCT and enhance the efficacy, safety, and value for money of technologies for preventing and treating diabetes.

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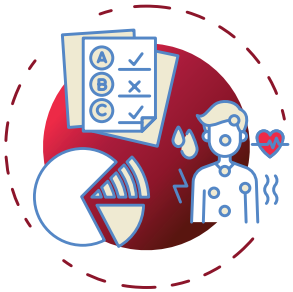
REDDIE Approach

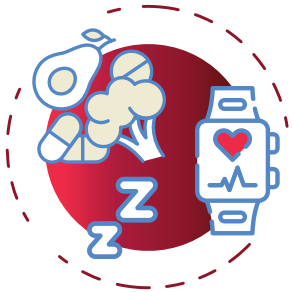
One of the main hurdles using RWD is to understand the difference in outcomes from interventions in RCTs and in RWD. Our approach will compare outcomes from RCTs with matched and unmatched populations from RWD databases to understand the efficacy to effectiveness gap and the factors that affect this.

How we are going to do it:

- Develop a set of evidentiary standards to be pre-specified and used in analysis of real-world/synthetic data and applied to different types of regulatory advice and/or health-technology assessment
- Address aspects that would enable moving towards a standard data quality framework reproducible across different RWD/ synthetic data sources that link RWD with data collected during RCTs
- Enhance performance and efficiency of large RCTs by developing standardised methods to access RWD/synthetic data
- Define methodological standards for the regulatory acceptability of RWD, and/or synthetic data
- Test the ability of machine learning methods to help identify relevant RWD, and/or synthetic data
- Assess and validate machine-learning methods to harness a large amount of unstructured data

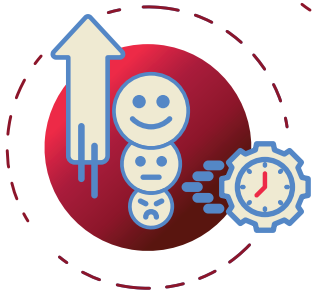
Currently, limited patient information from clinical trials are available.





National registries have a huge amount of patient data, so called real-world data, RWD.

By making RWD available to regulators, payers and guideline-makers,



better decisions regarding new therapies can be made more efficiently and quickly.

Resulting in better outcomes for People living with diabetes.