

About REDDIE



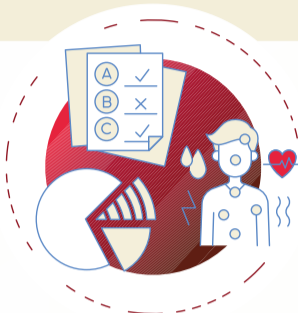
Real-world evidence for decisions in diabetes.

Randomised controlled trials (RCT) are the cornerstone of evidence-based medicine. However, the digitisation of real-world data (RWD) 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.

Use of randomised controlled trials (RCT)

- Collected data are limited in size
- Recruiting of patients with specific characteristics



Use of real-world data (RWD)

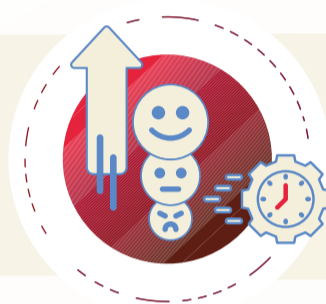
- Data referring to the general population
- Better characterisation of people with conditions



- REDDIE will use data from four large national registries (Sweden, Denmark, Germany and England), including data from devices, wearables, and electronic health records.
- REDDIE will use this RWD to elucidate the gap between outcomes in RCTs and RWD studies
- Together with regulatory and Health technology assessment (HTA) authorities and patient organisations
- REDDIE will develop and validate state-of-the-art modelling techniques using synthetic data to better assess outcomes of interventions using RWD

REDDIE Concept

Generate standards for RWD use for the evaluation of medicines and other interventions by regulatory authorities and HTA bodies.



Resulting in better care for people living with diabetes



THE PROCESS



Define a research question addressed in an RCT that needs to be extended with RWD



Identify homogeneous groups of people treated in the same way



Develop techniques to harmonise the available RWD and to generate synthetic data



Test the research question on the RWD or synthetic data, which constitute a much bigger cohort than the one available in RCTs



Get much faster answers to the research question



Obtain new standards for conducting "virtual trials" that can supplement and support RCTs



DATA COMPARISON

Randomised controlled trial (RCT) data

- Obtained in tightly controlled settings
- Descriptive of highly selected populations
- Time- and resource-intensive
- Subject to regulatory approval

Real-world data (RWD)

- Gathered from a variety of sources (e.g., hospital data, medical devices)
- Referring to wider, more inclusive populations
- Expensive to gather and maintain, but less than RCTs
- Their non-primary use can raise privacy concerns

Synthetic data

- Artificially generated through algorithms
- Resembling behaviours observed in real populations
- Inexpensive to produce and store
- Compliant with data protection regulations

Effective use of all three data types can improve the efficiency of clinical research.

www.reddie-diabetes.eu



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