Development, optimisation and implementation of artificial intelligence methods for real-world data analysis in regulatory decision-making and health technology assessment along the product lifecycle.

Real4Reg

Unlocking Real-World Data with AI

Funded by
the European Union

Key facts

- **Project funded by the European Union - Horizon Europe**
- **Grant agreement ID: 10109535310**
- **Funding: 7 million €**
- **January 2023 - December 2026**
- **Coordinator: BfArM (Federal Institute for Drugs and Medical Devices)**

10 consortium partners from 6 European countries

AARHUS UNIVERSITY

Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde I.P.

EUPALS

CSC

Fraunhofer SCAI

UNIVERSITY OF EASTERN FINLAND

EIWH

DZNE

Federal Institute for Drugs and Medical Devices
HDL

DAC
DATA ANALYTICS CENTRE

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

4 data-sharing countries

- **Denmark**
- **Finland**
- **Germany**
- **Portugal**

The three overall objectives of Real4Reg, considering the application of real-world evidence (RWE) from real-world data (RWD) in regulatory decision-making and health technology assessment (HTA) are:

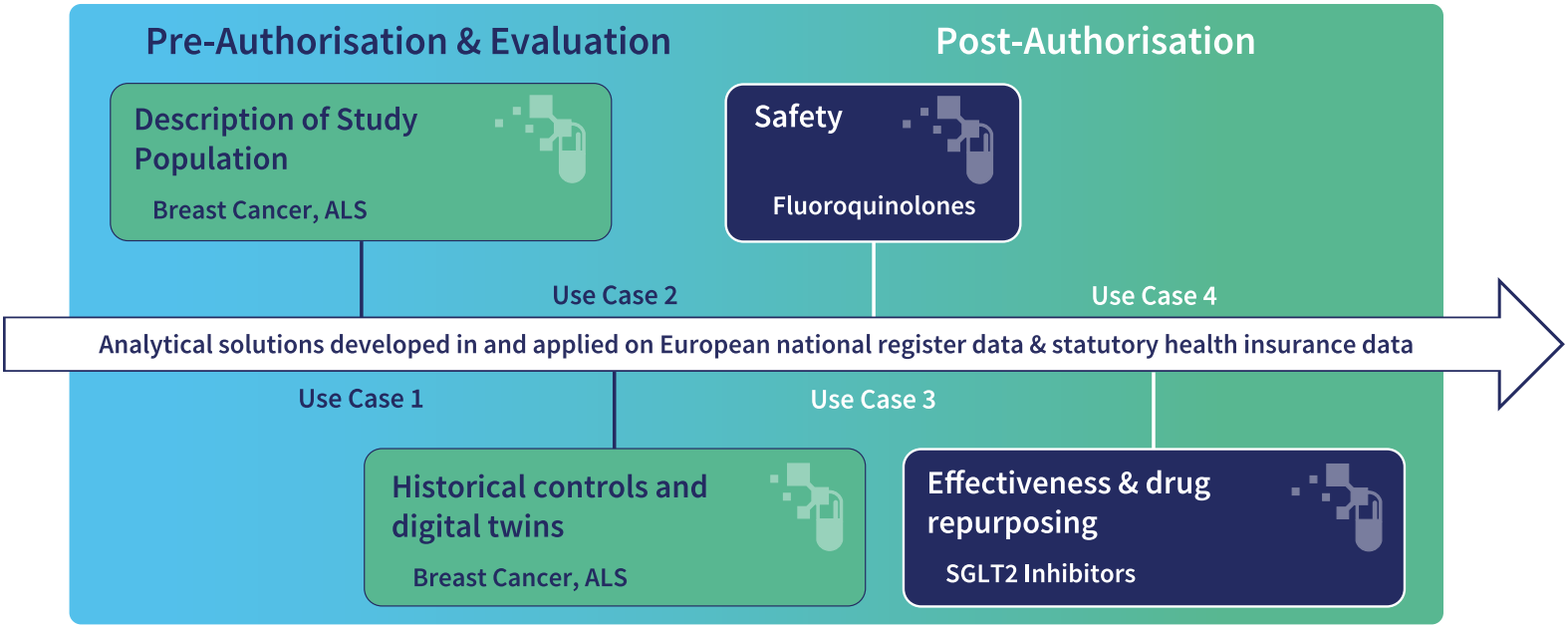
- **to enable the use of RWD/RWE**
- **to establish the value of RWD/RWE**
- **to impact RWD/RWE use and analyses**

Aims

Use Cases

Real4Reg will employ use cases for the development, optimisation, and implementation of artificial intelligence and machine learning methods for RWD analyses in regulatory decision-making and HTA.

The selected use cases have practical relevance along the product life cycle.



Use Case 1

Aims to assess the value of RWD from national healthcare registers and claims data in generating high-quality, accessible, population-based information on amyotrophic lateral sclerosis (ALS) and breast cancer: diagnosis, treatment, outcomes.

Use Case 2

Seeks to demonstrate how RWD can contribute to answering questions that are not typically answered by clinical trials, due to ethical or practical issues. These questions need to be answered for regulatory evaluation and HTA, in the improvement of external validity, statistical power and precision.

Use Case 3

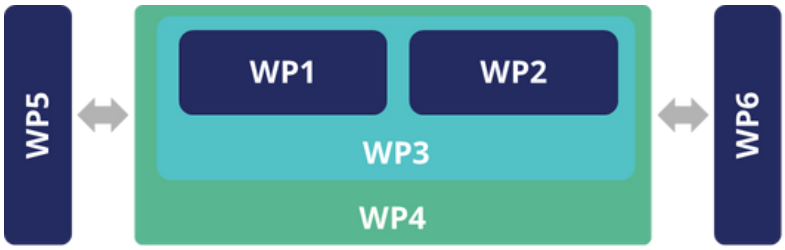
Preparation of a good practice example for safety analyses of RWD for the post-authorisation stage and the improvement of methods for risk estimation in observational data. It will also evaluate the impact of regulatory warnings on the use of broad-spectrum antibiotics.

Use Case 4

Aims to prepare a good practice example for drug effectiveness and drug repurposing analyses of RWD for the drug post-authorisation stage.

Work Packages

Real4Reg comprises six distinct Work Packages (WPs) that operate in close interaction from the start.



	WP Leader:
WP1 – Use cases in Pre-Authorisation & Evaluation	Danish Medicines Agency (DAC)
WP2 – Use cases in Post-Authorisation	University of Eastern Finland
WP3 – Methodology & Tools	Fraunhofer SCAI
WP4 – Contextualisation	Federal Institute for Drugs and Medical Devices
WP5 – Project Management and Coordination	Federal Institute for Drugs and Medical Devices
WP6 – Dissemination, Exploitation and Communication	Infarmed

The Real4Reg project will:

- **provide solutions for the data analytical needs of health regulatory and HTA bodies across the EU in the field of RWD and synthetic data;**
- **deliver usable standards for regulatory decision-making and HTA;**
- **define new and optimised guidance and training.**

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