



Unlocking Real-World Data with AI

The Real4Reg project – work in progress

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Demystifying Real-World Data – Insights for Patients, 14 October 2024



Agenda

01. The Real4Reg project and its impact
02. Methods: Use cases, datasets, work packages
03. First results
04. Outlook

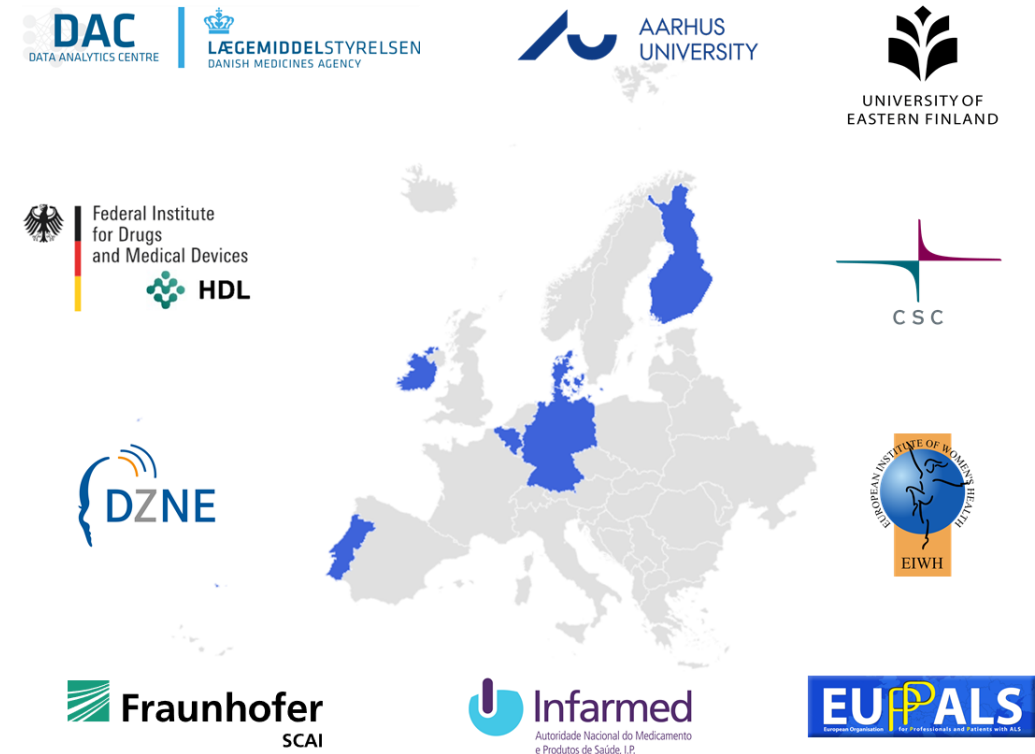
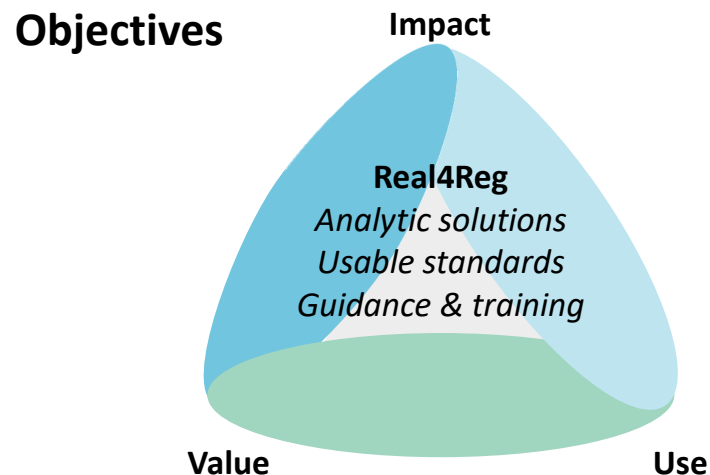
The Real4Reg project and its impact

The Real4Reg project

Real4Reg: Development, Optimisation & Implementation of AI-Methods for RWD Analyses in Regulatory Decision-Making & HTA along the Product Life-Cycle

Duration: 2023-2026, ~ 7 Mio €

Consortium: 10 Partners, 6 EU countries, Lead: BfArM



Expected impact

Society

- Better use of citizens' data
- More efficient decisions on treatment options
- Better information for citizens on RWD use through targeted communication

Regulation & HTA

- Workflows and training to facilitate evaluation of RWE
- Multi-database studies to support decisions
- Supporting development of harmonized standards regarding RWE (guidance)
- Improved RWE analysis capacities

Science

- Guidance & training to improve RWD research methodology
- Implementation of modern AI/ML methodology

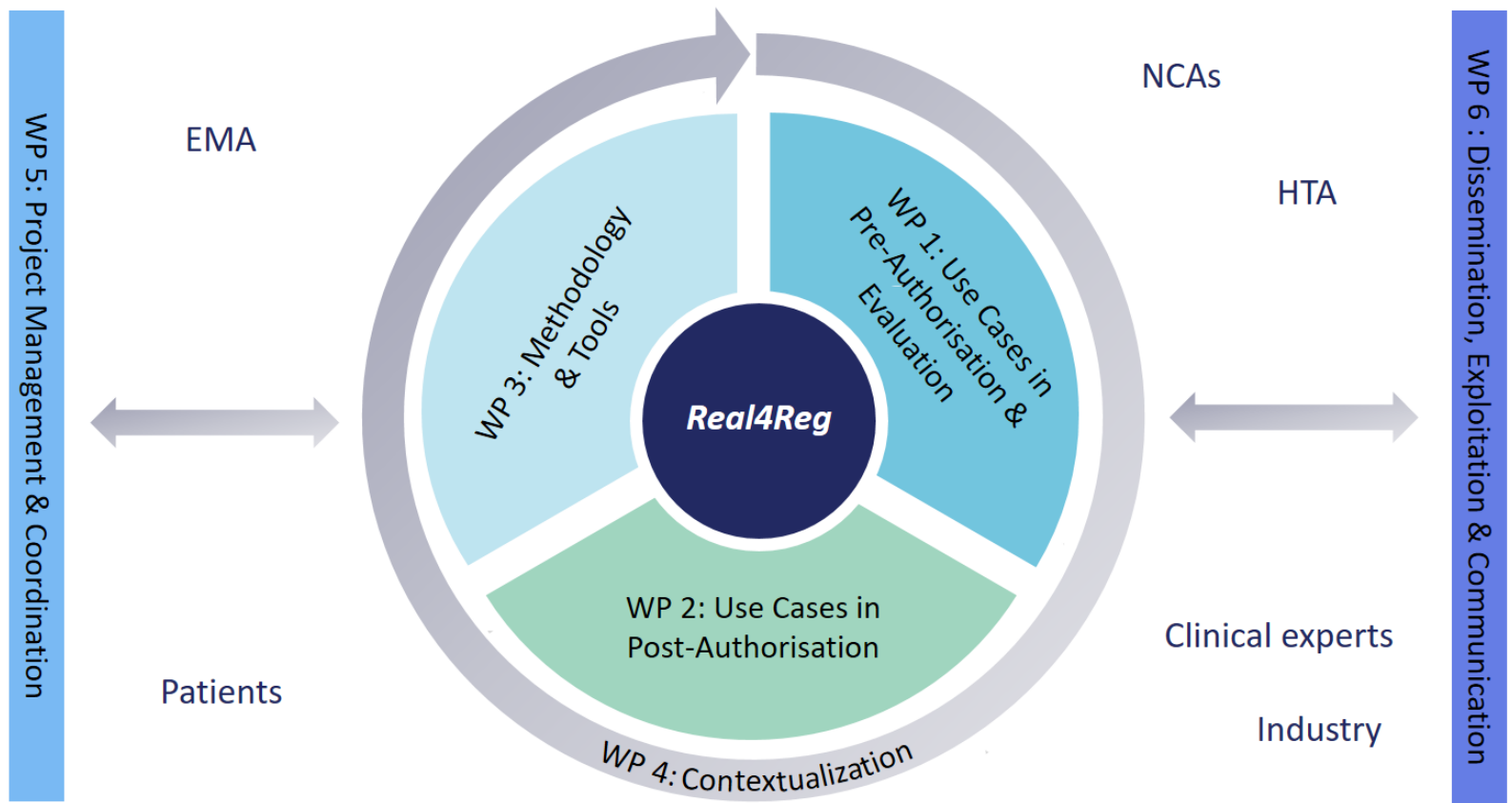
Industry

- Improved understanding of acceptability of RWE
- Guidance & training to inform staff about use of RWD

RWD – real-world data
RWE – real-world evidence
HTA – health technology assessment
AI – artificial intelligence
ML – machine learning

Methods:
Use cases, datasets, work packages

Work packages



*The Advisory Board

WP – work package
EMA – European Medicines Agency
NCA's – national competent authorities
HTA – health technology assessment

Use cases



Description of datasets

Country	Type of data	Size of source population	Variables
Denmark	National health and administrative register data	5.9 million	Procedures, diagnoses, prescriptions, healthcare service use, date of birth, sex
Finland	National and administrative register data and claims	5.6 million	Procedures, diagnoses, prescriptions, healthcare service use, sociodemographic data
Germany	Claims data	72.8 million	Reimbursed diagnoses, procedures and prescriptions, sociodemographic data
Portugal	Registry data	10.3 million	Reimbursed dispensed medicines, procedures, disease and treatment registries, date of birth, sex

- Patient-level data is pseudonymized
- Data does not leave the data holding organizations
- Processing in line with General Data Protection Regulation (EU 2016/679)
- Approval from the respective local Data Protection Agencies where applicable

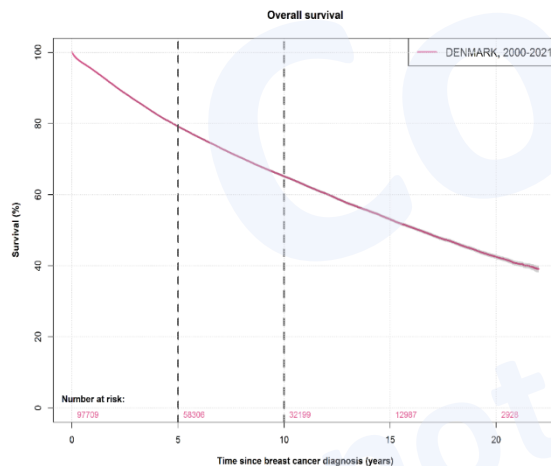
First results



Progress in the analytical WPs

Work package 1

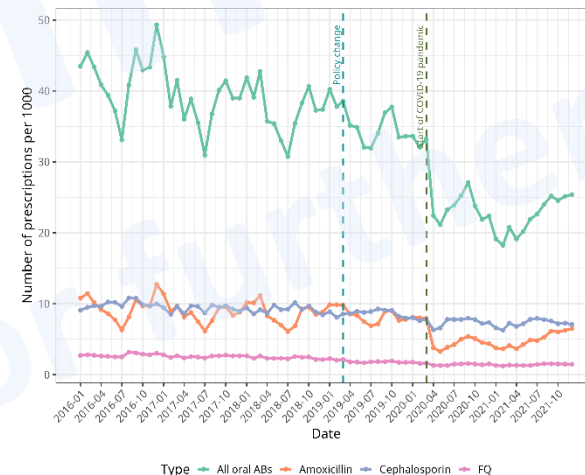
- Analysis of ALS & breast cancer patient characteristics finalized for Denmark



Overall survival of breast cancer patients in Denmark

Work package 2

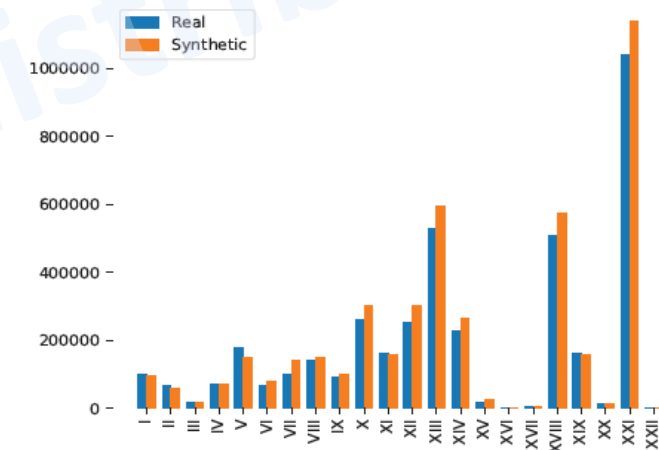
- Analysis of fluoroquinolone prescribing trends finalized in Finland



Monthly prescription rates of antibiotics in Finland

Work package 3

- Initial tests of AI algorithms for generating synthetic data



ICD code chapters

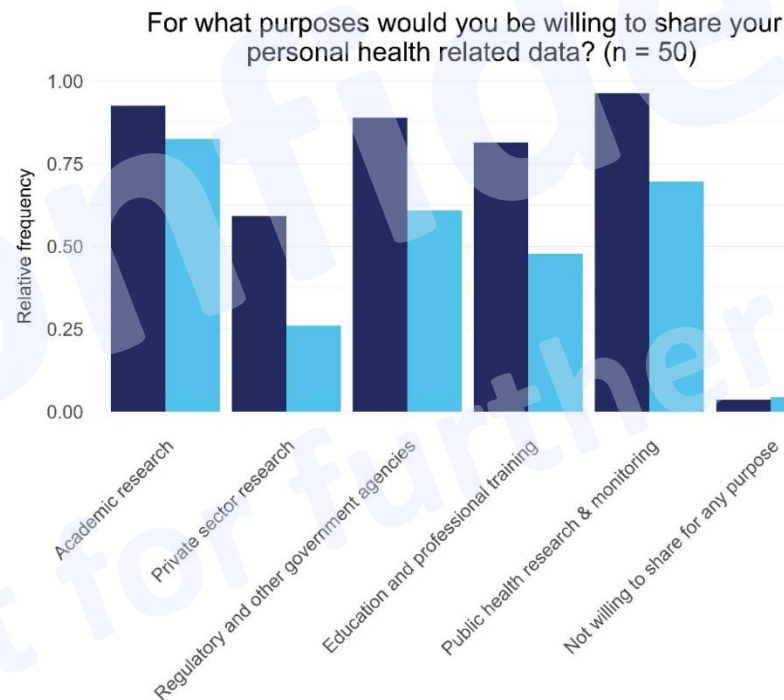
ALS – amyotrophic lateral sclerosis
AI – artificial intelligence
ICD – International classification of diseases

First results from contextualization WP4: survey

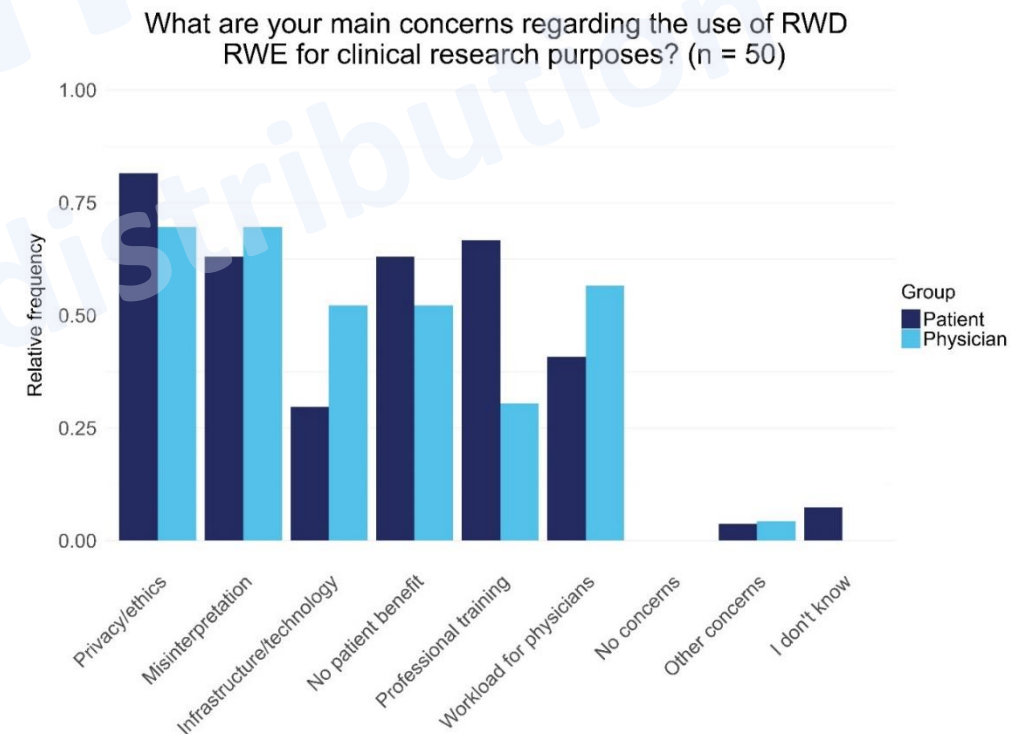
Survey among patients & physicians

- N = 53, 51% patients
- 85% members of patient organisations or medical associations
- Patients: 30% already share data for research purposes

Great willingness to share personal health data



Main concern regarding RWD use for research: privacy/ethics and misinterpretation



RWD – real-world data
RWE – real-world evidence

Outreach

Conferences and publications

- Presentation of Real4Reg project at national & international conferences
- Position paper to introduce Real4Reg project, objectives and expected impact submitted

Workshops

- Conduction of workshops to inform public and gather input on research
- First RWD workshop conducted 11/2023
- Second RWD workshop and patient event today (10/2024)



RWD – real-world data



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About Research topics Information for Patients News & Events

Real4Reg – Unlocking Real-World Data with AI

Real4Reg is a consortium of ten European institutions which aims to promote the use of real-world data (national healthcare registers and claims data) to support the regulatory decisions about medicines. Real4Reg will take advantage of ground-breaking technologies such as artificial intelligence and machine learning. The structure and approach of our project aim to facilitate the implementation of the effective use of real-world data in regulatory decision-making and health technology assessment.

About the Real4Reg Project

Download brochure



www.real4reg.eu

Outlook



Outlook

Scientific

- Full data access expected
- More scientific results available
- AI methodologies being evaluated



Outreach

- Continued interaction with related projects:
MetReal Cluster Meeting on 31 October 2024
- Continued interaction with EMA & other regulators:
MetReal / EMA workshop in February 2025
- Patient-adapted communication
- Scientific publications of project results



AI – artificial intelligence
EMA – European Medicines Agency

Thank you!

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