Real World Evidence

Project Lead:
Elena Valkanova

Deliverable:
White paper/Guideline

Key Achievements This Quarter:

Project approved

Proposed Project End Date:
Q4 2026

Applying Advanced Data Privacy Methods to Real World Data (RWD)

Project Scope:

The goal of this project is to develop a comprehensive, cross-disciplinary resource to support individuals and organisations in applying advanced privacy-preserving techniques to real-world data (RWD). Given the evolving landscape of privacy regulations and the increasing complexity of data sources – including integrating machine learning (ML), artificial intelligence (AI) and large language models (LLMs) into healthcare pipelines – this project will serve as a critical foundation for advancing privacy-preserving data integration frameworks for RWD.

Project Status:
Green

Project Accepting New Members: Yes

Deliverables & Targets Planned for the Next Quarter:

- Call for Volunteers
- Kick-Off Meeting

Project Leads:
Matt Baldwin, Ksenia Titorenko & Paramita Chakraborty

Deliverable:
White paper & webinar series

Key Achievements This Quarter:

Draft chapters of white paper ready for internal review

Proposed Project End Date:
Q2 2027

Estimands for RWD/RWE

Project Scope:

White paper title:
Establishing Robust Estimands in Real-World Evidence

Webinar series title:
At the Intersection of Estimands and Target Trial Emulation (TTE) for RWE

Project Status:
Green

Project Accepting New Members: No

Deliverables & Targets Planned for the Next Quarter:

- Plan webinars for Q1/Q2 2026
- Stable initial version of white paper

Project Leads:
Likhita Kolli, Sujith M & Tuhin James Paul

Proposed Project End Date:
Q4 2026

Project Scope:
We aim to publish a white paper which will explore multiple models available for missing data imputation, and share with the wider group the potential of each model and its efficiency in dealing with different kinds of missing data. The model efficiency will be compared using a single open-source simulated dataset.

Deliverable:
White paper

Missing Data Imputation in RWD: Exploration of Multiple Techniques on Open-Source Data

Project Status:
Green

Project Accepting New Members: Yes

Key Achievements This Quarter:

- Planning of Hackathon for US Connect
- Semi-fresh start with new volunteer pool

Deliverables & Targets Planned for the Next Quarter:

- Test data for Hackathon
- Hackathon organisation

Project Leads:
Berber Snoeijer & Ashwin Rai

Proposed Project End Date:
Q4 2025

Project Scope:
Real-world data sources have been used for many years in the pharmaceutical industry. They are useful for validating research questions and protocol set-up, patient and centre selection, post-registry safety follow-up and market access. However, the use for regulatory submissions is new. For this, the requirements are more stringent, and we need a robust process to assess quality, accuracy, appropriateness of the data and compliance to regulatory requirements.

How are we going to set ourselves up for success? We shall focus on:

- Selecting the appropriate data source
- Ensuring the data sources are accurate and traceable
- How we assess the quality of the data.

Deliverable:
- Guideline review blog posts
- Data vendor feasibility blog posts
- White paper

Quality and Reusability of Real World Data

Project Status:
Green

Project Accepting New Members: No

Key Achievements This Quarter:

White paper initial version ready for internal review

Deliverables & Targets Planned for the Next Quarter:

Finalise white paper for public review

Project Lead:
Dhruba Sikdar

Deliverable:
White paper

Key Achievements This Quarter:

Public review – no comments received

Proposed Project End Date:
Q4 2025

RWD Guideline for Programming and Analysis Processes

Project Scope:
The project will bring together statistical programmers across pharma to collaborate and provide their input to create an RWE guideline/white paper for the industry.

Project Status:
Green

Deliverables & Targets Planned for the Next Quarter:

Finalise white paper for publishing

Project Accepting New Members:
No (project is closing after publication)

Project Leads:
Parag Shiralkar

Proposed Project End Date:
Q4 2025

Project Scope:
The scope of the project includes developing collaterals for submission of real-world data through mutual discussion, knowledge, and experience sharing by industry colleagues. The collaterals will be developed by undertaking research of draft guidance documents on real-world evidence by regulatory bodies, and by analysing members' lessons learnt from completed case studies. The scope of this project will include submission of real-world data obtained from primary and widely used real-world data sources. These may include key electronic health record sources, patient reported outcomes, widely used and accepted claims data sources, and other commonly used observational data. This project will also touch upon the data curation and ingestion processes pertaining to clinical operational as well as submission data.

Deliverable:
White paper of DRG Reviews for submitting RWD

Submitting Real World Data

Project Status:
Green

Project Accepting New Members: No (project is closing after publication)

Key Achievements This Quarter:

Completed the cDRG review

Deliverables & Targets Planned for the Next Quarter:

Review summary of cDRG with regards to RWD data submissions

Project Leads:
Berber Snoeijer, Alexa Parliyan & Sanket Kalyankar

Proposed Project End Date:
Q4 2026

Project Scope:
The scope of the project includes developing awareness of data standards specific to real-world data to support regulatory purposes. Common data models (CDMs) and taxonomies that are specific to the most commonly used real-world data sources by industry, member companies and regulatory bodies across the globe will be in scope, such as electronic health record sources, patient reported outcomes, widely accepted claims data sources, and other commonly used observational data. OMOP and the OHDSI community will be the focus, and will be evaluated against other CDMs and standards (such as PCORnet, Sentinel and CDISC).

Deliverable:
White paper

Using OMOP and Other Real World Data Standards to Support Regulatory Submissions

Project Status:
Green

Project Accepting New Members: Yes

Key Achievements This Quarter:

- White paper outlined
- Started collecting content per chapter

Deliverables & Targets Planned for the Next Quarter:

First chapter's initial text available