

# Real World Evidence

## Table of Contents

1

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

2

Estimands for RWD/RWE

3

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

4

Quality and Reusability of Real World Data

5

Real World Evidence (RWE) in Japan

6

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

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

## 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.

Q4 2026

Proposed  
End Date

White paper/  
guideline

Deliverable  
Type

Elena  
Valkanova

Lead

- New members joined
- Started Draft Paper

Key Achievements  
This Quarter:

- First version of part 2 (review of the privacy guidelines - relevance to the RWD methods)

Deliverables &  
Targets Planned for  
the Next Quarter:



Project Status: Green  
Accepting New Members

- New team members joined, team split into two workstreams
- Each workstream meets twice per month
- Expect draft paper part 1 related to the guidance by Q2

Project Status

# Estimands for RWD/RWE

## Scope

The focus of this project is on best practices of RWD estimands, not on their implementation using data standards. The team formed has representation from the PHUSE Implementation of Estimands (ICH E9 (R1)) using Data Standards project team, which has a white paper nearing publication, and the Estimands Implementation Working Group (EIWG) sub-team on HTA and RWE, both with estimands expertise, along with representation from teams under the RWE Working Group. The EIWG sub-team on HTA and RWE started in late 2022, and has a cross-functional membership, including regulators, statisticians, epidemiologists and health economists.

Q2 2027

Proposed  
End Date

White paper &  
webinar series

Deliverable  
Type

Ksenia Titorenko,  
Matt Baldwin &  
Paramita Chakraborty

Leads

- PHUSE US Connect workshop
- Estimands webinar execution and planning

Key Achievements  
This Quarter:

- Webinar 4 May
- Stable draft white paper by end of Q2

Deliverables &  
Targets Planned for  
the Next Quarter:



Project Status: Green

- WS1: Still working on draft paper - target stable draft by Q2
- WS2: Upcoming webinar, 21 May 2026

Project Status

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

## 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.

Q4 2026

Proposed  
End Date

Hackathon at the  
PHUSE US Connect

Timelines and planning  
of white paper

White paper

Deliverable  
Type

Key Achievements  
This Quarter:

Deliverables &  
Targets Planned for  
the Next Quarter:

Likhita Kolli,  
Sujith Mididoddi &  
Tuhin James Paul

Leads



Project Status: Amber  
Accepting New Members

- Input for both white paper and algorithms created. Not yet collated to a document

Project Status

# Quality and Reusability of Real World Data

## 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 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).

Q2 2026

Proposed  
End Date

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

Deliverable  
Type

White paper for public  
review

Key Achievements  
This Quarter:

- Collate any comments if given
- Prepare final document for release

Deliverables &  
Targets Planned for  
the Next Quarter:

Ashwin Rai &  
Berber Snoeijer

Leads



Project Status: Green

- White paper in public review

Project Status

# Real World Evidence (RWE) in Japan

## Scope

Use cases of RWE specific to industry/regulations in Japan:

- To accelerate drug development
- For post marketing surveillance (PMS)
- For preventative actions

Q4 2026

Proposed  
End Date

Sessions at the Japan SDE

- Plan detailed contents:  
June
- Deliver the session at the  
Japan SDE: November

Deliverable Type

William Kuan,  
Yasunari Sadatsuki  
& Yosuke Nishida

Leads

Started planning for the  
PHUSE SDE in Japan

Key Achievements  
This Quarter:

Detailed planning for the  
PHUSE SDE in Japan

Deliverables &  
Targets Planned for  
the Next Quarter:



Project Status: Green

- We have started planning for the PHUSE SDE in Japan, and we will proceed with more detailed planning once the SDE Chairs and themes are confirmed.

Project Status

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

## 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).

Q4 2026

Proposed  
End Date

White paper

Deliverable  
Type

Alexa Parliyan,  
Berber Snoeijer &  
Sanket Kalyankar

Leads

PHUSE US Connect  
workshop  
Content for first draft of  
white paper ready

Key Achievements  
This Quarter:

Internal review of white  
paper and alignment of  
chapters

Deliverables &  
Targets Planned for  
the Next Quarter:



Project Status: Green  
Accepting New Members

- Content for first draft of white paper ready

Project Status