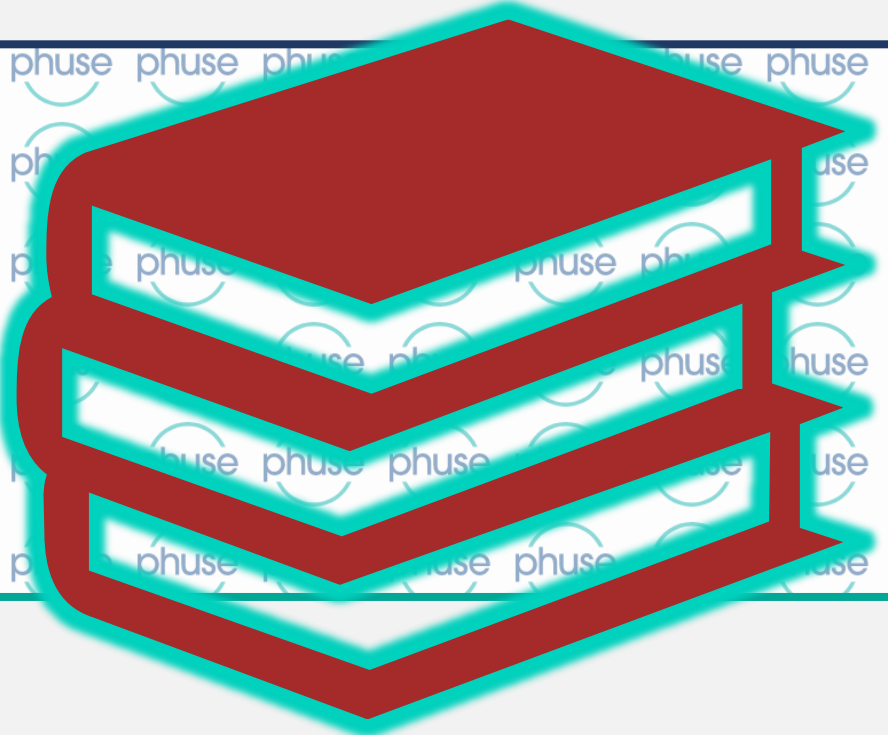


PP26: The PHUSE Real-World Evidence Project

The Real-World Data (RWD)/Real-World Evidence (RWE) working group is a cross-functional team of individuals from various sectors within the pharmaceutical industry. Our goal is to facilitate the creation, collection, and use of RWE to inform healthcare decision-making. To achieve this, we have established four key workstreams:

1. RWE Playbook
2. RWE programming and analysis guidance
3. RWE Submission Requirements
4. Quarterly Community Forums

Rabia Ahmad (GSK)
Berber Snoeijer (clinline)
Parag Shiralkar (Sumptuous DS)



RWE Playbook

The RWE playbook will provide guidance on processes and requirements for conducting RWE analyses, such as study design, data sources, analysis techniques, and reporting standards.

RWE Programming and Analysis Standards

This workstream will develop guidance materials on specific databases and algorithms commonly used in RWE analysis, as well as templates in Python, R, and SAS for consistent and accurate analyses.

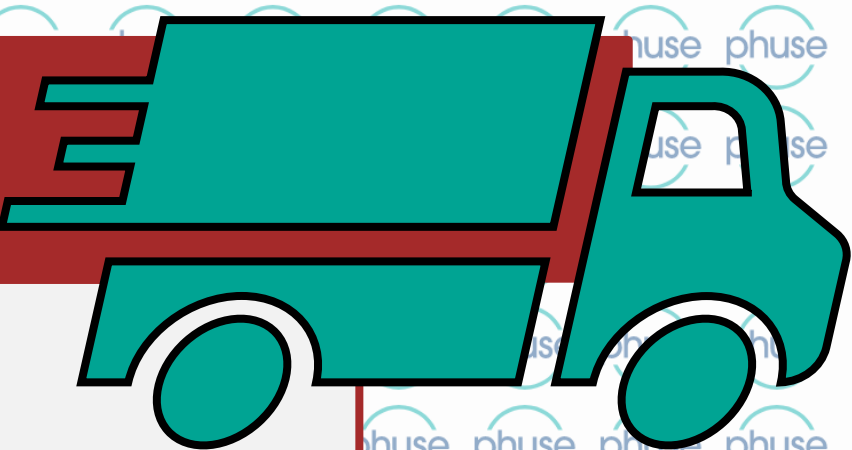
Quarterly Community Forums

The quarterly community forums offer a collaborative knowledge-sharing platform to discuss best practices, challenges, and opportunities related to RWE.

RWE Submission Requirements

The group will compile a list of submission guidelines for working with regulatory bodies when using RWE to inform healthcare decision-making, such as, data sharing, ethical considerations, and documentation requirements.

Ongoing & Planned

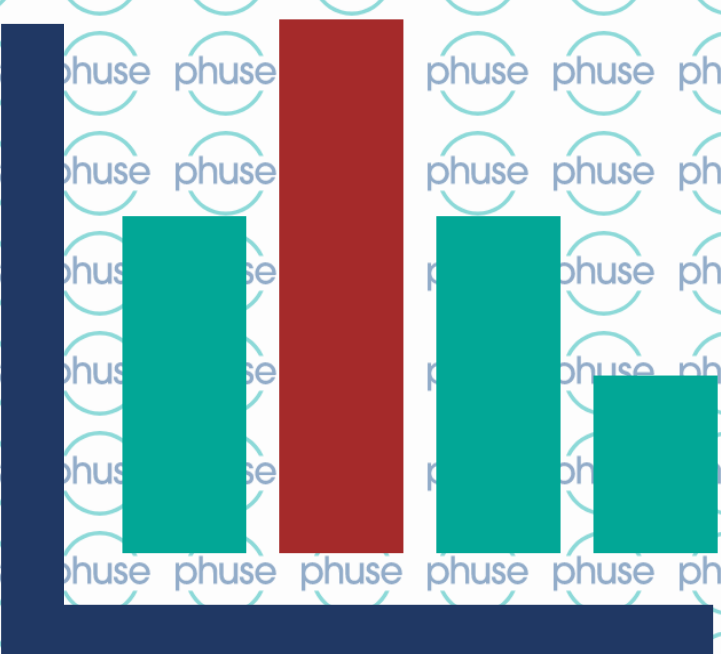


Deliverables

- ✱ Use of Data Standards in RWE Trials *
- ✱ RWE Playbook
- * *Under review*

Community Forums

- ✱ Data Transformation: Observational Medical Outcomes Partnership (OMOP)
- ✱ RWD/RWE Programming & Reporting Standards
- ✱ Designing your RWD study



With many thanks to the RWE Working Group Leads

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Graphics courtesy of: Ahmad Imam

Past Deliverables & Community Forums

Deliverables

- ✓ Identify And Prioritize Future Real-World Evidence Project, July 2020

Community Forums

- ✓ The Role of Statisticians and Statistical Programmers in Real-World Data Analysis, June 2022
- ✓ Ingestion and Standardization of Real-World Data, October 2022
- ✓ Submitting Real-world Data, January 2023



For more information or to join the RWE working group

