

# PP25: PHUSE Real-World Evidence Working Group

The 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 RWD/RWE to inform healthcare decision-making. To achieve this, we have established four key workstreams:

1. Real-World Evidence Guidance
2. Submitting Real-World Data
3. Quality and Reusability of Real-World Data
4. Real-World Data guideline for Programming and Analysis Processes

## Quarterly Community Forums

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

## Community Forums

### Prior:

- ✦ Role of Statisticians and Statistical Programmers in Real World Data Analysis
- ✦ Ingestion and Standardization of Real-World Data
- ✦ Submitting Real World Data
- ✦ Designing Your RWD Study- Is your Data Fit for purpose?

### Upcoming:

- ✦ Experiences with Adapting RWD into CDISC Submission Standards"- 5th October 2023

The corresponding information and recordings of community forums are available via the PHUSE advanced hub. See

<https://advance.phuse.global/display/WEL/PHUSE+Community+Forum>

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## Real-World Data Programming and Analysis Processes

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

## Submitting Real-World Data

In collaboration with industry partners, the RWE working group is in the process of developing the following collaterals for industry:

- 1) Checklist to collect the contents of RWE trials relevant for programming function
- 2) Draft addendum to data reviewer's guide
- 3) Communication plan and white paper for timely discussion of data traceability and provenance issues with regulatory bodies

## Quality and Reusability of Real-World Data

The project focusses on RWD sources and their usability for regulatory purposes. This includes:

- 1) Selection of appropriate data sources
- 2) Traceability and accuracy of data sources
- 3) Assessing the quality of data

## Real-World Evidence Guidance

The project focusses on sharing knowledge and experience in utilization of real-world data by:

- 1) Developing cases and seed examples via open-source Q&A posts and chatbot technology
- 2) Raising awareness in industry about RWE issues through PHUSE education

For more information or to join the RWE working group

## Contact the Authors and RWE Group Leads:

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