Real World Evidence



Working Group Scope

The Real World Evidence Working Group aims to support, address and answer pertinent questions around real-world evidence. The Working Group is dedicated to sharing across the PHUSE Community (through Community Forums) and aligning on the best industry practices. Some of the questions we intend to address are:

- What are the requirements, technologies and processes needed to use real-world evidence as a source for data analysis?
- What are the requirements, technologies and processes needed to incorporate real-world evidence into clinical trials?
- What are the requirements, technologies and best practices needed to support the use of real-world evidence as part of regulatory submissions?

Current Projects

Estimands for RWD/RWE

Quality and Reusability of Real World Data

Real World Evidence Guidance

RWD Guideline for Programming and Analysis Processes

Submitting Real World Data

All projects are currently calling for volunteers. If you would like to get involved, email workinggroups@phuse.global.

PHUSE Collaborative Projects

Real-world Evidence (RWE) in Japan

Resources

Requirements and Recommendations for Regulatory Submissions

Archive

Real World Evidence Project



Working Group Lead Berber Snoeijer

b.snoeijer@clinline.eu

Berber Snoeijer started in clinical research in 1997 as a biometrician and has since then worked with clinical data in different functions. In 2001 she started a CRO -Biometric Support - aimed at the data management, data analysis and reporting of clinical trials. In 2011 she started as an R&D manager dedicated to investigating and utilising the potential of real-world data from electronic health records. This resulted in many different solutions including a full reporting system to give feedback information to clinical research professionals. Berber is experienced with software and database engineering, process engineering and improving efficient utilisation and interaction of people based on management drivers. Nowadays, she uses these skills and knowledge to help life science companies assess, design and improve business solutions and processes at smaller and larger scales.



parag.shiralkar@sumptuous-ds.com

Parag Shiralkar has over 19 years of experience in the pharmaceutical and biotech industry. He has taken operational, managerial and executive leadership roles in the functions of data operations, biostatistics and statistical programming. In his tenure, Parag has worked on almost all aspects of data operations and analysis involved in clinical trial data used in the context of the drug development process. He has led the execution of statistical programming activities for various regulatory submissions in the Immunology. Rare Disease, Infectious Disease and Oncology therapeutic areas. Parag's current career interests include frameworks for appropriate use of real-world data (RWD) for clinical as well as medical research, risk-managed use of open-source technologies, and application of AI/ML in the statistical reporting environment. He has completed master's degrees in biostatistics and in business administration. Parag is President of Sumptuous Data Sciences and is based out of New Jersey, USA.



Working Grou Ashwin

Ashwin.Rai@evide

With over 15 years of experience across pharma, life sciences and I Rai is a prominent leader in RWF Director of Data Science & Analyti ThermoFisher company, Ashwin le that develops cutting-edge AI algc models in domains such as RWE, studies. His expertise includes imp and predictive analytics projects on monitoring and management o predictive healthcare modeling, pa disease progression analysis, adv medicine, and proactive healthcar diverse data sources such as clini labs and pharmacy data. Ashwin a s Real World Data Solutions team data feasibility assessments, valid third-party real-world data. Ashwir been instrumental in expanding Ev science business, forging collabor and experts to deliver innovative,

Ashwin's commitment to pushing I data science for healthcare advan underscored by his abstracts and in AI and ML within the healthcare selection and presentation of his *A* prestigious PHUSE/FDA Data Sci Challenge in both 2020 and 2024. accomplishments highlight Ashwir driving innovation and leveraging address critical challenges in heal

Ashwin holds a master of science analytics from Northwestern Unive Overland Park, Kansas.