

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

[Best Data Practices for Rare Disease Patient Foundations and Researchers](#)

[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

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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.



Working Group Lead
Parag Shiralkar

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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.



Ashwin Rai
Evident

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With over 15 years of experience across pharma, life sciences and AI, Ashwin Rai is a prominent leader in RWE. Director of Data Science & Analytics at ThermoFisher company, Ashwin leads teams that develop cutting-edge AI algorithms and models in domains such as RWE, clinical studies. His expertise includes imaging and predictive analytics projects – from monitoring and management of predictive healthcare modeling, patient disease progression analysis, advanced medicine, and proactive healthcare. He leverages diverse data sources such as clinical labs and pharmacy data. Ashwin leads the Real World Data Solutions team in performing data feasibility assessments, validating third-party real-world data. Ashwin has been instrumental in expanding Evident's science business, forging collaborations with experts to deliver innovative, high-quality solutions.

Ashwin's commitment to pushing the boundaries of data science for healthcare advancement is underscored by his abstracts and presentations in AI and ML within the healthcare domain. His selection and presentation of his work at the prestigious PHUSE/FDA Data Science Challenge in both 2020 and 2024 are notable accomplishments highlighting Ashwin's driving innovation and leveraging data to address critical challenges in healthcare.

Ashwin holds a master of science in data analytics from Northwestern University, Overland Park, Kansas.