RWD Quality Challenges – Different Perspectives

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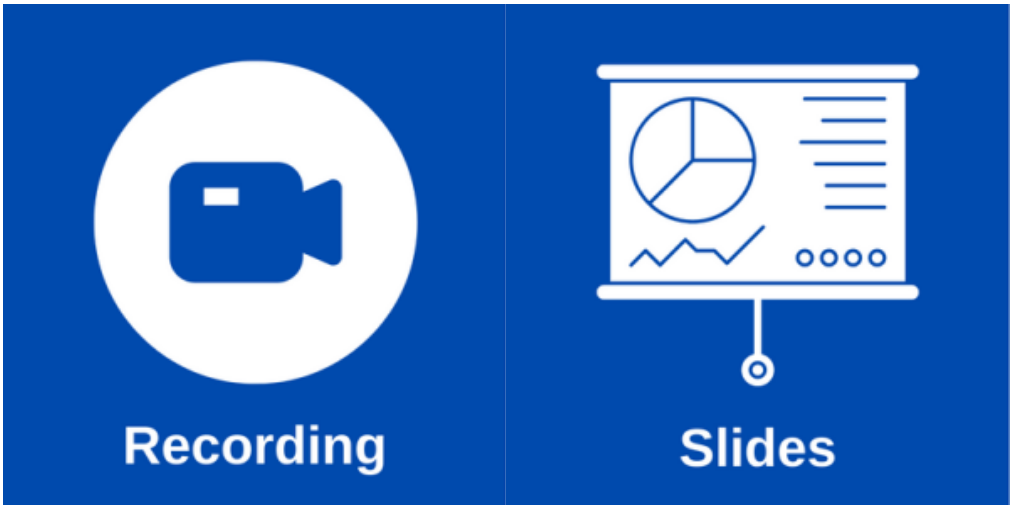
As the opportunities for using RWD in drug development have grown, so too has the attention to its quality. Our RWE working group has an ongoing project that seeks to address questions on this topic, ranging from how to assess quality to ensuring accuracy and traceability. Recent discussions at our round-tables at PHUSE's CSS have also highlighted varying experiences of data quality – not meeting expectations, challenges to validate findings from RWD, inconsistent coverage across geographies and over time. We will revisit this topic again in our January Community Forum, from the perspectives of the applicant/sponsor, data vendor and regulator – with the hope of having all angles covered and finding common learnings. Cheryl will start with her perspective and will share some inspection case examples, including challenges encountered with conducting inspections, issues with RWD quality, and the lessons we can learn from challenges and issues that arose during OSI's review of studies using RWD/RWE to support regulatory decision making. Kris will follow with his perspective from the other side of the table – sharing his experiences and the critical role of data provenance in real-world evidence (RWE) studies. Data provenance, described as a 'fingerprint' for data, allows researchers to trace information through curation, transformation and analysis steps, addressing the challenges posed by the substantial increase in data volume in RWE studies. This Community Forum took place over Teams on 18 January.

Catch up here!
This Community Forum took place on 18 January 2024. Catch up by viewing the recording or reading the slides. Got a question for the presenters? Submit it to the online Disqus forum posted below!



Presenter	Bio

Dr Cheryl Grandinetti, *FDA*

Dr. Grandinetti is a reviewer in the Good Clinical Practice Assessment Branch of the Division of Clinical Compliance Evaluation /Office of Scientific Investigations in CDER /FDA. She provides regulatory and scientific oversight for CDER-assigned bioresearch monitoring activities and scientific and clinical oversight to FDA field investigators. She pa rticipates as a subject matter expert in GCP inspections to evaluate data integrity, quality, and safety of human subjects in clinical trials, including in studies using RWD.

Kris Wenzel, *MMS*

Kris Wenzel is a Senior Manager, Data Science with over 30 years of global IT technical and managerial experience and proven leadership with large scale projects, digital transformation, data engineering and analytics. Mr. Wenzel holds a Masters in Business Administration with a concentration in Finance and a Bachelor of Science Engineering with a Concentration in Computer Engineering.