Basel Epidemiology Seminar

BBS
Basler Biometric Section

Real-World Data Quality – Assessing data quality and demonstrating fitness-for-purpose

BBS/BES Seminar
Wednesday 15th March, 2023 from 14:30-17:00 CET
Virtual meeting

14:30 - Welcome from the organizing committee

Introduction to Data quality (moderation: Susan Edwards, Roche)

14:30-14:45	What is data quality, and how data types differ in terms of data quality	Massoud Toussi (IQVIA)
14:45-15:00	RWD for regulatory decisions	Nicole Mahoney (Novartis)

Short Q&A clarification questions

Session 1: Assessing the quality of data sources (moderation: Susan Edwards, Roche)

15:05-15:20	EHDEN: Data Quality Dashboard	Clair Blacketer (Janssen)
15:20-15:35	EU Data quality framework	Daniel Morales (EMA)

Short Q&A clarification questions

Break

Session 2: Case studies - Demonstrating fitness-for-purpose (moderation: Fred Sorenson, Xcenda)

15:45-16:00	COPD case study - The Use of the OMOP Common Data Model in Health Technology Assessment	Dalia Dawoud (NICE)
16:00-16:15	Data quality in Flatiron	Spencer James (Roche/Genentech)

Short Q&A clarification questions

Panel Discussion Session: Perspectives on future needs for data quality assessment
(moderation: Sigrid Behr, Novartis)

16:15-16:25	Transcelerate - How to bridge from framework to fitness for purpose demonstration?	Gracy Crane (Roche)
16:25-17:00	Panel discussion	All speakers, Q&A from audience

17:00 - Closure of the meeting

Biographies (in alphabetical order of last name)

Clair Blacketer is a Director in the Observational Health Data Analytics group at Janssen Research & Development where she focuses on the standardization and quality of a variety of real-world data sources. She is an active member of the OHDSI community where she leads both the Common Data Model and Data Quality working groups. Clair is also pursuing a PhD in Medical Informatics at Erasmus Medical Center under the tutelage of Peter Rijnbeek and Martijn Schuemie.

Gracy Crane is a cancer biologist by training with a Master in Biomedical Research and a Ph.D. in Cancer Biology. She has also completed post-doctoral training fellowships at Oxford University (UK) and Massachusetts Institute of Technology (USA). She has over 12 years of years of experience in the pharmaceutical industry, in varying roles including medical and scientific affairs, clinical development, health outcomes research and real world data. For the past 5 years, she has worked on leading the real world evidence strategy for molecules within the rare cancer space as part of the global Data Science team of the personalized health care department at Roche. Currently, she is the RWD policy lead and Chapter Lead within the Global Regulatory Policy team at Roche. She has authored many publications on this topic and has presented in many international conferences. Gracy is also part of a number of external steering/working groups including the ISPOR RWD transparency Initiative (https://www.ispor.org/strategic-initiatives/real-world-evidence/real-world-evidence-transparency-initiative), the CIOMs working group on RWD/E guidelines, and the Duke Margolis RWE Collaborative. She is also a co-author on the HARPER work: https://onlinelibrary.wiley.com/doi/full/10.1002/pds.5507

Dr Dalia Dawoud is Associate Director (Research) at the National Institute for Health and Care Excellence (NICE). She holds a PhD in pharmaceutical policy and economics from King's College London. Her current work is focused on the use of real-world evidence to inform drug development and health care decision making where she is leading NICE input into European funded projects such as IMI EHDEN and HORIZON 2020 HTx. She serves on a number of research projects advisory boards and as Associate Editor for ISPOR journal Value in Health.

Spencer James is a physician scientist currently working as a Principal Data Scientist at Genentech. His work at Genentech has focused on advancing inclusive research for Genentech and Roche through the use of real world data and evidence and by developing new methods and metrics for assessing burden of disease, forecasting rare diseases, and measuring data representativeness. Spencer's academic background includes medicine, population health, and biochemistry. Prior to Roche, he led research teams at University of Washington's Institute for Health Metrics and Evaluation, studied medicine at Dartmouth, and developed disease surveillance technologies for population health research.

Nicole Mahoney is the global regulatory policy lead for real-world evidence at Novartis. In this role, she contributes to a number of collaborative policy efforts, including the Duke Margolis RWE Collaborative and a TransCelerate project designed to promote RWD audit readiness. Prior to Novartis, Nicole was the head of Regulatory Policy at Flatiron Health, where she helped advance the use of real-world evidence for regulatory decision making in oncology, and catalyzed the formation of the RWE Alliance.

Christoph Meier is the chief pharmacist of the hospital pharmacy at the University Hospital Basel and professor of clinical pharmacy and epidemiology at the Department of

Pharmaceutical Sciences at the University of Basel. He is the head of an academic unit called 'Basel Pharmacoepidemiology Unit' which conducts research in pharmacoepidemiology, drug safety and drug utilization.

Dr Daniel Morales, is a senior clinical epidemiologist within the Data Analytics Taskforce at the European Medicines Agency (EMA). Until recently he was a European Commission appointed Independent Scientific Expert to the EMA Pharmacovigilance Risk Assessment Committee. Dr Morales background is in clinical general practice and academia.

Massoud Toussi is the Global Lead for Evidence from Secondary Data Category in IQVIA. He is medical doctor and pharmacoepidemiologist by training. He has more than 20 years of experience leading research teams in conducting real world studies. His is co-author of several peer-reviewed articles, books and guidelines on this topic.