



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

BBS/BES Seminar

Wednesday 15th March, 2022 from 14:30-17:00 CET

Virtual meeting

This Seminar is free of charge. However, please register here:

<https://docs.google.com/forms/d/e/1FAIpQLSf6V7Ahrm9o0HytitlTIXDFfuqLV-bHnhBpTuaKeUstozlsWg/viewform>

Outline

The value of Real-World Evidence to support decision making in drug development and healthcare has been recognized by many stakeholders. Data quality and fitness for the specific research purpose are the foundation of reliable evidence generation. Various frameworks and guidance documents are developed by regulators and research collaborations to clarify expectations and to provide guidance on best practice.

This seminar aims at reviewing proposed frameworks as well as concrete use cases to exchange learnings and expectations on the assessment of data quality and fitness-for-purpose of Real-World Data. The first session of the seminar will focus on assessing the overall quality of a data source (e.g. EHR database, registry, data network, etc.). The second session will include feasibility and validation efforts to demonstrate the quality of the data in the context of a specific study/research question.

Agenda

Welcome from the organizing committee

Introduction to Data quality

1. What is data quality, and how data types differ in terms of data quality (Massoud Toussi, IQVIA)
2. RWD for regulatory decisions (Nicole Mahoney, Novartis)

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

3. EHDEN: Data Quality Dashboard (Clair Blacketer, Janssen)
4. EU Data quality framework (Daniel Morales, EMA)

Break

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

5. COPD case study - The Use of the OMOP Common Data Model in Health Technology Assessment (Dalia Dawoud, NICE)
6. Flatiron case study (Genentech speaker tbd)

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

7. Transcelerate - How to bridge from framework to fitness for purpose demonstration ? (Gracy Crane, Roche)

Closure of the meeting