Methodological Advances in Regulatory Real World Evidence Generation Systems: Perspectives from Sentinel and DARWIN-EU

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Panel introduction

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- The views expressed in this presentation represent those of the presenter and do not necessarily represent the official views of the U.S. FDA.

Data Infrastructure Update
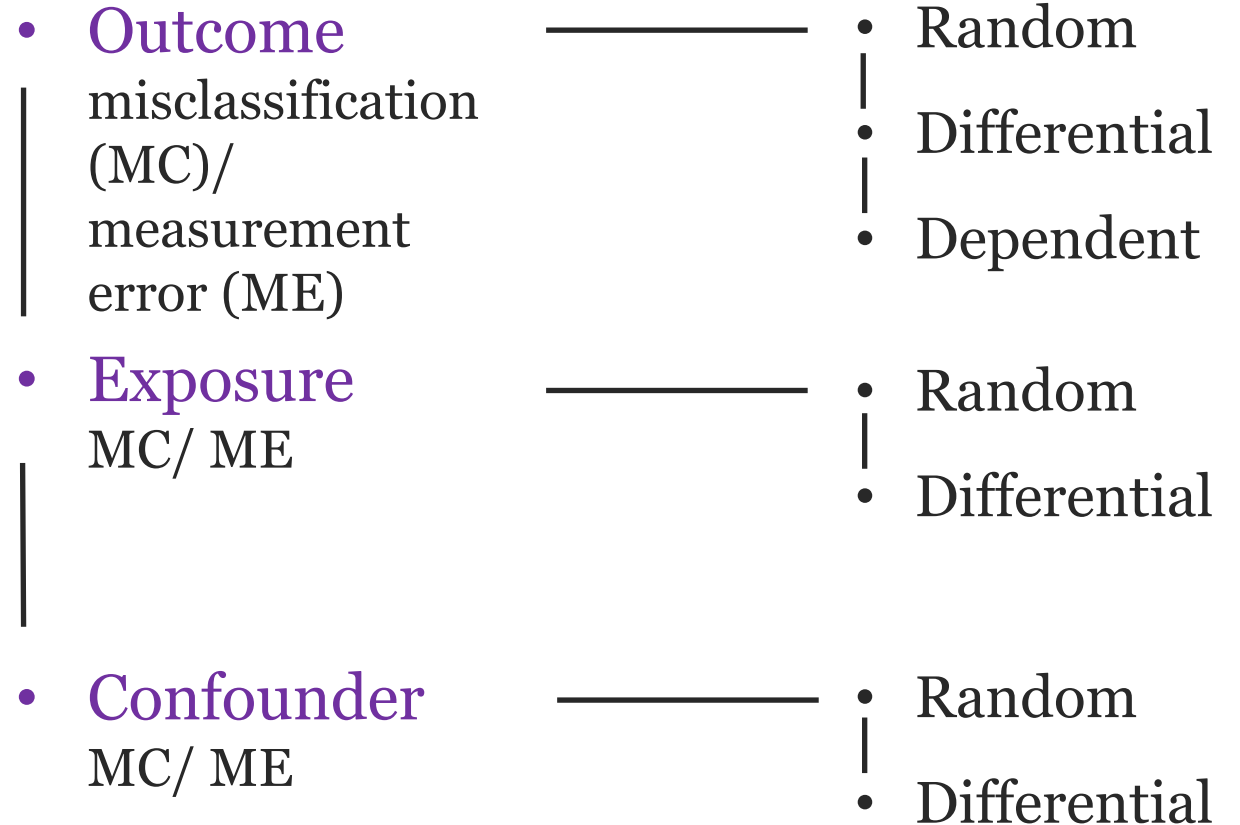
(Sebastian Schneeweiss)

Bias as an Obstacle to Causal Inference

1. Confounding

2. Selection bias

3. **Information bias**

The error mechanisms

- Outcome misclassification (MC)/ measurement error (ME)
  - Random
  - Differential
  - Dependent

- Exposure MC/ ME
  - Random
  - Differential

- Confounder MC/ ME
  - Random
  - Differential

Porta M. A Dictionary of Epidemiology 5th ed. 2008

Data Quality Map

Information Bias Mechanisms

Data Curation & Provenance

Measurement

Validation studies

Measurement Characteristics

Quant Bias Analysis

Data Quality Dimensions Relevant for Causal Inference

Data Continuity	Patients receive treatments/assessments by a range of providers during their journey through the healthcare continuum: • More longitudinally complete data throughout the care continuum will reduce surveillance related issues/bias
Data Granularity	Detailed clinical and other information improves the measurement of exposure, confounders, and outcomes: • More granular data are preferred for a broad range of etiologic studies
Data Chronology	The accurate chronology of confounder, exposure and outcome measurement is critical for causal inference: • Unclear chronology can lead to a range of biases, like reverse causation, adjustment for intermediates, immortal time

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