DIA 2018
GLOBAL ANNUAL MEETING
BOSTON | JUNE 24-28

Session #278: Challenges and Opportunities in Data Access and Methodology Development for Post-Market Generic Drug Monitoring

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Learning Objectives

1. Analyze the technical challenges involved in the comparison between the branded and generic products in post-market stage;
2. Identify current data sources that enable post-market evaluation and quantitative approaches for signal detection;
3. Evaluate the level of evidence associated with every study design of post-market research.

Presentations & Speakers:

- Postmarketing Surveillance of Generic Drugs at the FDA: Current Methods and Future Directions
  Sarah K Dutcher, PhD, MS
  Epidemiologist, OSE, CDER
  FDA, United States

- Leveraging Administrative Claims and Electronic Health Record Data
  Joseph Ross, MD, MHS
  Associate Professor of Medicine and Public Health
  Yale University School of Medicine, United States

- Authorized generics as a tool for assessing the safety and effectiveness of generic drugs
  Joshua Gagne, DrSc, PharmD
  Associate Professor of Medicine and Epidemiology
  Brigham and Women's Hospital and Harvard Medical School, United States

Panel discussion and Q&A (30') upon conclusion of the presentation (3x15')

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Panel Question 1:

- What types of post marketing analysis on what source of data can make you feel confident to draw a conclusion?

Panel Question 2:

- What regulatory/socio-economic impacts can be made by conducting post marketing researches?