Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products Guidance for Industry
Real-World Evidence Webinar Series
November 4, 2021
1:30-2:30 pm ET

Agenda

Webinar Goal: Provide an overview of recent draft guidance and address questions from the public about the draft guidance titled Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products

1:30 pm Welcome
Susan C. Winckler, RPh, Esq, CEO, Reagan-Udall Foundation for the FDA

1:35 pm Opening Remarks
John Concato, MD, MS, MPH, Associate Director for Real-World Evidence Analytics, Office of Medical Policy, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

1:40 pm Overview of Draft Guidance
Speakers:
  • Michael Blum, MD, MPH, Deputy Director, Office of Pharmacovigilance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
  • Wei Hua, MD, PhD, MHS, MS, Supervisory Associate Director in Oncology and RWE, Division of Epidemiology I, Office of Pharmacovigilance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

2:10 pm Question and Answer
Moderator: Susan Winckler, RPh, Esq
Panelists:
  • Michael Blum, MD, MPH
  • John Concato, MD, MS, MPH
  • Wei Hua, MD, PhD, MHS, MS
  • Natasha Pratt, PhD, Acting Team Leader, Senior Epidemiologist, Division of Epidemiology II, Office of Pharmacovigilance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

2:25 pm Closing Remarks
Susan C. Winckler, RPh, Esq.

2:30 pm Adjourn