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Webinar Goal: Provide an overview of recent draft guidance and address questions from the public about the draft guidance titled *Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products*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1:40 pm Overview of Draft Guidance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

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