Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products
Real-World Data Guidance Webinar Series
February 11, 2022
11 AM -12 PM ET

Agenda

Webinar Goal: Provide an overview of recent draft guidance and address questions from the public about the draft guidance titled Considerations for the Use of Real-World Data and Real-World Evidence To Support Regulatory Decision-Making for Drug and Biological Products

11 am Welcome
Susan C. Winckler, RPh, Esq, CEO, Reagan-Udall Foundation for the FDA

11:05 am 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

11:10 am Overview of Draft Guidance
Speakers:
- Tala Fakhouri, PhD, MPH, Associate Director for Policy Analysis, Office of Medical Policy Initiatives, Office of Medical Policy, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
- Stefanie Kraus, JD, MPH, Senior Regulatory Counsel, Office of Regulatory Policy, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

11:40 am Question and Answer
Moderator: Susan C. Winckler, RPh, Esq
Panelists:
- John Concato, MD, MS, MPH
- Tala Fakhouri, PhD, MPH
- Stefanie Kraus, JD, MPH

11:55 am Closing Remarks
Susan C. Winckler, RPh, Esq

12:00 pm Adjourn