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Webinar Goal: Provide an overview of recent draft guidance and address questions from the public about the draft guidance titled *Considerations for the Use of Real-World Data and Real-World Evidence To Support Regulatory Decision-Making for Drug and Biological Products*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11:10 am Overview of Draft Guidance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

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