Real-World Evidence: Considerations Regarding Non-Interventional Studies for Drug and Biological Products

Real-World Data Guidance Webinar Series

Thursday, May 30, 2024

2 – 2:45 PM Eastern Time

Agenda

Webinar Goal: Provide an overview of and address questions from the public about the draft guidance titled *Real-World Evidence: Considerations Regarding Non-Interventional Studies for Drug and Biological Products*.

2 pm Welcome

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

2:05 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

2:10 pm Overview of Draft Guidance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

2:25 pm Question and Answer

Moderator: **Susan C. Winckler, RPh, Esq**

Panelists:

- **John Concato, MD, MS, MPH**
- **Tala Fakhouri, PhD, MPH**
- **Stefanie Kraus, JD, MPH**

2:40 pm Closing Remarks

Susan C. Winckler, RPh, Esq

2:45 pm Adjourn

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