Integrating Randomized Controlled Trials for Drug and Biological Products Into Routine Clinical Practice

Real-World Data Guidance Webinar Series

November 22, 2024

1 – 1:45 p.m. Eastern Time

Agenda

Webinar Goal: Provide an overview of and address questions from the public about the draft guidance titled *Integrating Randomized Controlled Trials for Drug and Biological Products Into Routine Clinical Practice*.

1 pm Welcome

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

1:05 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

1:10 pm Overview of Draft Guidance

Speakers:

- **Leonard Sacks, MBBCh**, Associate Director, Clinical Methodologies, Office of Medical Policy, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
- **Heather Stone, MPH**, Health Science Policy Analyst, Clinical Methodologies, Office of Medical Policy, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

1:25 pm Question and Answer

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

Panelists:

- **John Concato, MD, MS, MPH**
- **Leonard Sacks, MBBCh**
- **Heather Stone, MPH**

1:40 pm Closing Remarks

Susan C. Winckler, RPh, Esq

1:45 pm Adjourn

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