Data Standards for Drug and Biological Product Submissions Containing Real-World Data

Real-World Evidence Webinar Series

December 3, 2021

1-2 pm ET

Agenda

Webinar Goal: Provide an overview of recent draft guidance and address questions from the public about the draft guidance titled *Data Standards for Drug and Biological Product Submissions Containing Real-World Data.*

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1:10 pm Overview of Draft Guidance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:

- **Scott Gordon, PhD**, Senior Health Informatics Officer, Office of Strategic Programs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
- **Massoud Motamed, PhD, MS,** Biology Reviewer, Office of Tissue and Advanced Therapies, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration

1:40 pm Question and Answer

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

Panelists:

- **John Concato, MD, MS, MPH**
- **Scott Gordon, PhD**
- **Massoud Motamed, PhD, MS**

1:55 pm Closing Remarks

Susan C. Winckler, RPh, Esq

2:00 pm Adjourn

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