# Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products Guidance for Industry

Real-World Data Guidance Webinar Series

January 28, 2022

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**Webinar Goal:** Provide an overview of recent draft guidance and address questions from the public about the draft guidance titled *Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products Guidance for Industry*

**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**1:10 pm Overview of Draft Guidance**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:*

- **Ansalan Stewart, PhD**, Health Science Policy Analyst, Division of Clinical Trial Quality, Office of Medical Policy, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
- **Kerry Jo Lee, MD**, Associate Director for Rare Diseases, Rare Diseases Team, Division of Rare Diseases and Medical Genetics, Office of New Drugs, Center for Drug 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**
- **Ansalan Stewart, PhD**
- **Kerry Jo Lee, MD**

**1:55 pm Closing Remarks**

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

**2:00 pm Adjourn**

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