

Lessons Learned from Trial Replication Analyses: Findings from the DUPLICATE Demonstration Project

Virtual Public Webinar

May 10, 2022 | 12:00 pm – 2:30 pm ET

Agenda

On May 10, 2022, the Duke-Margolis Center for Health Policy will convene a public workshop, under a cooperative agreement with the U.S. Food and Drug Administration, to review findings from the RCT-DUPLICATE Demonstration Project. The discussion will build on a previous public workshop convened by Duke-Margolis on [February 16, 2021](#), which shared preliminary results from trial replication efforts with the goal of better understanding the strengths and limitations of observational studies. The current workshop will report on additional results and further elaborate on lessons learned from RCT-DUPLICATE; potential implications for regulatory decision-making will also be explored.

12:00 pm **Welcome and Introductions**

Rachele Hendricks-Sturupp, Duke-Margolis Center for Health Policy

12:05 pm **Opening Remarks**

John Concato, U.S. Food and Drug Administration

12:15 pm **Overview of Technical Findings: The RCT-DUPLICATE Demonstration Project**

Objectives: The results of the completed RCT-DUPLICATE demonstration project, including 32 trial emulations, will be presented. Presenters will briefly review the scientific methodology and focus on presenting results with important insights regarding key findings beyond the replication studies presented at the February 2021 workshop.

Moderator: **Rachele Hendricks-Sturupp**, Duke-Margolis Center for Health Policy

Presenters:

- **Shirley Wang**, Brigham and Women's Hospital
- **Sebastian Schneeweiss**, Brigham and Women's Hospital

1:15 pm **Break**

1:20 pm Stakeholder Reactions to Result Findings, and Implications

Objective: Panelists will comment on the presented results and offer lessons learned from the demonstration project. The panel will also consider the implications of these results for potential use in regulatory decision-making.

Moderator: **Rachele Hendricks-Sturup**, Duke-Margolis Center for Health Policy

Panelists:

- **Ken Quinto**, FDA, CDER
- **Melvin Olson**, Novartis
- **Issa Dahabreh**, Harvard T.H. Chan School of Public Health
- **Steven Goodman**, Stanford University
- **Shirley Wang**, Brigham and Women's Hospital
- **Sebastian Schneeweiss**, Brigham and Women's Hospital

2:25 pm Concluding Remarks

Rachele Hendricks-Sturup, Duke-Margolis Center for Health Policy

2:30 pm Adjournment

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