Duke | MARGOLIS CENTER for Health Policy

Applying Lessons Learned from RWE in the Time of COVID-19 to the Future

Duke-Robert J. Margolis, MD, Center for Health Policy
Virtual Meeting
October 1, 2020

Meeting Objective: COVID-19 has disrupted the evidence-generation paradigm, resulting in the expanded use of novel technologies, data, and evidence. These new advancements not only improve clinical care and medical product development to fight the pandemic, but also have the potential to inform the future of drug development more broadly. This meeting will explore how COVID-19 has accelerated decision-maker understanding and use of real-world data (RWD) and real-world evidence (RWE) and its application in a post-COVID-19 environment.

1:00 pm **Welcome and Overview of the COVID-19 Response**
Mark McClellan, Duke-Margolis Center for Health Policy

1:10 pm **Keynote Address**
John Concato, U.S. Food and Drug Administration

1:25 pm **Session I: Embedding Practical Trials in EHRs: A Critical Approach for Leveraging Randomization, Objective Endpoints, Large Sample Size, and Minimal Data Collection to Deliver Decisive Results**

Objective: Robust evidence is needed to understand the safety and efficacy of new and repurposed therapies for treating COVID-19. While many clinical trials have been initiated, difficulties in recruiting patients and comparing results across trials have resulted in a lack of definitive evidence. Elsewhere, some observational approaches have shown both the potential promise and peril of generating information on the disease and patient outcomes from RWD sources collected at the point of care. Practical trials, in which randomization is maintained and EHR systems are leveraged to integrate data collection with clinical care to facilitate large-scale enrollment, have therefore emerged as an increasingly important plank in the international response to COVID-19. In this session, participants will discuss how practical trial networks with standardized protocols, adaptive design, and automated minimal data collection can improve evidence generation for COVID-19 therapeutics.

Moderator: Mark McClellan, Duke-Margolis Center for Health Policy
Panelists:

- **Robert Califf**, Verily and Google Health
- **Laura Esserman**, University of California, San Francisco
- **Adrian Hernandez**, Duke University School of Medicine
- **Pamela Tenaerts**, Clinical Trials Transformation Initiative
- **David Soergel**, Novartis

Moderated Q&A

2:10 pm **Session II: Transforming Outcome Capture: Advancing Routine Use of Digital Tools and Technology for Study Measurement**

Objective: The COVID-19 pandemic has limited patient and provider interactions, advancing the use of digital tools (e.g. sensors) and technology (e.g., remote monitoring and telemedicine) to capture data while limiting in-person patient and provider interactions. In this session, panelists will discuss how these tools and technologies are incorporated into clinical trials to maintain continuity and used in the real-world setting to capture data on patients who may not be interacting with the health care system and thus not in traditional real-world data sources (e.g., EHR, claims) during the COVID-19 pandemic. Panelists will also explore how increased use of these tools and technologies during COVID could inform data capture in future clinical trials and real-world studies across therapeutic areas. Finally, panelists will discuss developing and driving the broad adoption of novel endpoints in the post-COVID environment.

Moderator: Susan Dentzer, Duke-Margolis Center for Health Policy
Panelists:

- **Nancy Dreyer**, IQVIA
- **Leonard Sacks**, U.S. Food and Drug Administration
- **Ernesto Ramirez**, Evidation Health, Inc.
- **Crystal Browning**, Pfizer Inc.
- **Jennifer Goldsack**, Digital Medicine Society

Moderated Q&A

2:55 pm **Session III: Collaborating to Build a Better Real-World Data Infrastructure for Enhanced Post-Market Evidence**

Objective: During the COVID-19 pandemic, there has been unprecedented collaboration to share data, methods, and analytical approaches for observational studies to support rapid RWE generation. Collaborative efforts are particularly important in pursuing transparent and trusted observational analyses. In this session, participants will discuss how multi-stakeholder collaborations have supported COVID-19 research, including standardizing diagnosis and outcomes definitions, prioritizing research questions to answer in federated or parallel approaches, and developing aligned protocols for the conduct of observational studies. Together these efforts can advance the implementation of a high-quality real-world data ecosystem.

Moderator: Jeff Allen, Friends of Cancer Research
Panelists:

- **Susan Winckler**, Reagan-Udall Foundation for the FDA
- **Brian Anderson**, The MITRE Corporation
- **Griffin Weber,** Harvard University
- **Solomon Iyasu**, Merck & Co.

Moderated Q&A

3:35 pm **Fireside Chat**
Mark McClellan, Duke-Margolis Center for Health Policy
Amy Abernethy, U.S. Food and Drug Administration

3:55 pm **Closing Remarks**
Mark McClellan, Duke-Margolis Center for Health Policy

4:00 pm **Adjourn**