Duke | Robert J. Margolis, MD Center for Health Policy

A Framework for Regulatory Use of Real-World Evidence

1777 F St NW Conference Center • Washington, DC
September 13, 2017

9:00 a.m. **Welcome**
Mark McClellan, Duke-Margolis Center for Health Policy

9:10 a.m. **Opening Remarks from FDA**
Rich Moscicki, U.S. Food and Drug Administration

9:20 a.m. **Session I: Building a Framework for Regulatory Use of RWE**

Presentation: FDA's Perspectives on Enhanced Use of RWE
- Jacqueline Corrigan-Curay, U.S. Food and Drug Administration

Presentation: Clarifying the RWD and RWE Landscape
- Greg Daniel, Duke-Margolis Center for Health Policy

9:50 a.m. **Session II: Developing Fit-for-Purpose RWD**
Moderator: Mark McClellan

Speakers:
- Kevin Haynes, HealthCore
- Amy Abernethy, Flatiron
- Sally Okun, PatientsLikeMe
- Laura Esserman, University of California San Francisco School of Medicine

Moderated Discussion

11:00 a.m. **Break**

11:15 a.m. **Session III: Matching RWD and RWE to Regulatory Use Cases**
Moderator: Mark McClellan

Speakers:
- David Thompson, InVentiv Health
- Marc Berger, International Society For Pharmacoeconomics and Outcomes Research
- Jeffrey R. Curtis, University of Alabama at Birmingham
- Adrian Hernandez, Duke Clinical Research Institute

Moderated Discussion

12:15 p.m. **Lunch**

1:15 p.m. **Session IV: Pursing RWE Development Programs that Support Regulatory Use**
Moderator: Mark McClellan

Speakers:

- Amy Rudolph, Novartis
- Jacqueline Law, Genentech
- Symantha A. Melemed, Eli Lilly & Company
- Joanne Waldstreicher, Johnson & Johnson

Moderated Discussion

2:30 p.m. **Break**

2:45 p.m. **Session V: Charting a Collective Path Forward**
Moderator: Mark McClellan

Speakers:

- Greg Daniel, Duke-Margolis Center for Health Policy
- Jonathan Jarow, U.S. Food and Drug Administration
- Joe Selby, Patient-Centered Outcomes Research Institute
- Preston Hinkle, Cystic Fibrosis Foundation

3:45 p.m. **Closing Remarks**
Greg Daniel, Duke-Margolis Center for Health Policy

4:00 p.m. **Adjournment**