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:
- Marcus Wilson, HealthCore
- Sally Okun, PatientsLikeMe
- Laura Esserman, University of California San Francisco School of Medicine
- Amy Abernethy, Flatiron

Moderated Discussion and Audience Q&A

11:00 a.m. Break

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

Speakers:
- Marc Berger, ISPOR
- Jeffrey R. Curtis, University of Alabama at Birmingham
- Adrian Hernandez, Duke Clinical Research Institute

Moderated Discussion and Audience Q&A

12:15 p.m. Lunch Break
1:15 p.m.  Session IV: Pursing RWE Development Programs that Support Regulatory Use
   Moderator: Mark McClellan

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

   Moderated Discussion and Audience Q&A

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

   Moderated Discussion and Audience Q&A

3:45 p.m.  Closing Remarks
   Greg Daniel

4:00 p.m.  Adjournment