Leveraging Randomized Clinical Trials to Generate Real-World Evidence for Regulatory Purposes
The Westin Washington, DC City Center
1400 M St NW • Washington, DC 20005
July 11, 2019

Agenda

8:30 a.m. Registration

9:00 a.m. Welcome and Overview
Gregory Daniel, Duke-Robert J. Margolis, MD, Center for Health Policy

9:05 a.m. FDA Opening Remarks
Jacqueline Corrigan-Curay, U.S. Food and Drug Administration

9:15 a.m. Leveraging Randomized Designs to Generate RWE
Presenters:
• Robert Temple, U.S. Food and Drug Administration
• Lesley Curtis, Duke University

9:45 a.m. Selecting Interventions and Study Designs to Generate RWE
Moderator: Gregory Daniel
Presenters:
• Martin Landray, Oxford University
• Elaine Irving, GlaxoSmithKline
Panelists:
• Iris Goetz, Eli Lilly & Company
• Steven Piantadosi, Brigham and Women’s Hospital
• Louis Fiore, Veterans Affairs

11:00 a.m. Break

11:15 a.m. Outcome Measurement Based on Real-World Data
Moderator: Gregory Daniel
Panelists:
• Elizabeth Sugar, Johns Hopkins University
• Sean Tunis, Rubix Health
• Atul Butte, University of California at San Francisco
• David Madigan, Columbia University
• Bill Crown, OptumLabs
• Cathy Critchlow, Amgen

12:30 p.m. Lunch
1:30 p.m. Key Considerations for Blinding in Randomized Real-World Studies  
Moderator: Gregory Daniel  
Presenter: Simon Skibsted, Novo Nordisk  
Panelists:  
- Rita Redberg, University of California at San Francisco  
- Satrajit Roychoudhury, Pfizer  
- Nancy Dreyer, IQVIA  
- Peter Stein, U.S. Food and Drug Administration

2:45 p.m. Break

3:00 p.m. Real-World Designs and Implications for Causal Inference  
Moderator: Gregory Daniel  
Presenter: David Price, University of Aberdeen  
Panelists:  
- Vince Willey, HealthCore  
- Mark Levenson, U.S. Food and Drug Administration  
- Jesse Berlin, Johnson & Johnson  
- Lisa LaVange, University of North Carolina

4:15 p.m. Open Comment Period  
Gregory Daniel

4:45 p.m. Adjourn
Leveraging Randomized Clinical Trials to Generate Real-World Evidence for Regulatory Purposes

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Agenda

9:00 a.m. Key Takeaways from Day One
Mark McClellan, Duke-Robert J. Margolis, MD, Center for Health Policy

9:15 a.m. Monitoring Randomized Clinical Trials that Generate RWE

Focus Area 1: Sponsor Conduct and Monitoring Challenges
Moderator: Mark McClellan
Presenters:
  • Elaine Irving, GlaxoSmithKline
  • Loretta Jacques, GlaxoSmithKline
Panelists:
  • Adrian Hernandez, Duke University
  • Leanne Larson, Parexel (Association of Clinical Research Organizations)

Focus Area 2: Safety Monitoring
Moderator: Mark McClellan
Presenter: Nawar Bakerly, Salford Royal NHS Foundation Trust
Panelists:
  • Greg Ball, Merck
  • Ellis Unger, U.S. Food and Drug Administration

Focus Area 3: Maintaining Data Integrity
Moderator: Mark McClellan
Presenter: Martin Gibson, Salford Royal NHS Foundation Trust
Panelists:
  • Michael O'Neal, Bioclinica (Association of Clinical Research Organizations)
  • Paul Harris, Vanderbilt University

10:45 a.m. Break

11:00 a.m. Building a Framework for Randomized Clinical Trials: Barriers, Enablers, and Infrastructure
Moderator: Mark McClellan
Panelists:
  • Lesley Curtis, Duke University
  • Joanne Waldstreicher, Johnson & Johnson
  • Peter Stein, U.S. Food and Drug Administration
11:30 a.m. Open Comment Period  
Mark McClellan

12:15 p.m. Closing Remarks and Adjournment  
Mark McClellan

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