Unpacking Real-World Data Curation: Principles and Best Practices to Support Transparency and Quality

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1201 Pennsylvania Ave, NW Suite 500 • Washington, DC 20004
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Agenda

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

9:10 a.m. FDA Opening Remarks
David Martin, U.S. Food and Drug Administration

9:20 a.m. Session I: Transforming Raw Data into Research-Ready Data
Moderator: Gregory Daniel

Panelists:
• Cynthia Senerchia, Optum
• Andrew Norden, Cota
• Patrick Ryan, Janssen Research & Development
• Jeffrey Brown, Harvard Medical School & Harvard Pilgrim Health Care Institute

10:50 a.m. Break

11:00 a.m. Session II: Study Specific Data Curation to Establish a Fit-for-Purpose Dataset
Moderator: Mark McClellan

Panelists:
• Aylin Altan, OptumLabs
• Amy Abernethy, Flatiron Health
• Dan Riskin, Verantos
• Keith Marsolo, Duke University

12:30 p.m. Lunch
1:30 p.m.  Session III: Linking Multiple Data Sources  
Moderator: Gregory Daniel  
Panelists:  
- Shaun Grannis, Regenstrief Institute  
- Sam Roosz, Datavant  
- Steven Kundrot, TriNetX  

2:30 p.m.  Break  

2:45 p.m.  Session IV: Submitting Data Documentation for Traceability and Auditing  
Moderator: Mark McClellan  
Panelists:  
- Amy Abernethy, Flatiron Health  
- Jeremy Rassen, Aetion  
- Marc Overhage, Cerner  

4:00 p.m.  Closing Remarks and Adjournment