Duke | MARGOLIS CENTER *for* Health Policy

Advancing the Development and Implementation of Analysis Data Standards: Key Challenges and Opportunities

Tommy Douglas Conference Center • Silver Spring, MD
June 12, 2019

Agenda

9:00 a.m. **Welcome and Overview**

- **Gregory Daniel,** Duke-Robert J. Margolis, MD, Center for Health Policy

9:15 a.m. **Opening Remarks**

- **Laura Lee Johnson,** U.S. Food & Drug Administration

9:30 a.m. **Session I: FDA Efforts to Support Analysis Data Standards for Product Development and Review**

- **Matilde Kam,** U.S. Food & Drug Administration
- **Vaishali Popat,** U.S. Food & Drug Administration

10:15 a.m. **Break**

10:30 a.m. **Session II: Industry Experience with Data Standards During Product Development and Review**

Moderator: **Gregory Daniel**

Presenters:

- **Patti Compton,** Pfizer (PhRMA)
- **Stephen Hamburg,** GlaxoSmithKline (PhRMA)
- **Ralph DeMasi,** ViiV Healthcare

Panel Discussants:

- **Brenda Baldwin,** U.S. Food and Drug Administration
- **Michael Nessly,** ICON
- **Peter Van Reusel,** Clinical Data Interchange Standards Consortium
- **Lauren Shinaberry,** AbbVie
- **Nhi Beasley,** U.S. Food and Drug Administration

12:00 p.m. **Lunch**

1:00 p.m. **Session III: Additional Applications and Impact of Data Standards on Clinical Research and Development Outside of Industry**

Moderator: **Gregory Daniel**

Presenters:

- **Jose Galvez,** National Institutes of Health
- **Jackson Burton,** Critical Path Institute

Panel Discussants:

- **Frank Rockhold,** Duke University
- **Stephan Grupp,** Children's Hospital of Philadelphia

- **Shaojun Zhu,** University of California at Los Angeles (Society of Nuclear Medicine & Molecular Imaging)
- **Eileen Navarro-Almario,** U.S. Food & Drug Administration

2:00 p.m. **Break**

2:15 p.m. **Session IV: Key Opportunities to Improve the Implementation of Analysis Data Standards**
Moderator: **Matilde Kam**
Panel Discussants:

- **Weiya Zhang,** U.S. Food and Drug Administration
- **Yuki Ando,** Pharmaceuticals and Medical Devices Agency, Japan
- **Jessica Hu,** U.S. Food and Drug Administration
- **Russell Reeve,** IQVIA
- **Christopher Price,** Roche (PhUSE)

3:15 p.m. **Session V: Emerging Trends and Innovations for the Development and Use of Analysis Data Standards**
Moderator: **Gregory Daniel**
Presenter: **David Martin**, U.S. Food and Drug Administration
Panel Discussants:

- **Scott Gordon,** U.S. Food and Drug Administration
- **Tim Stoddard,** Flatiron Health
- **Peter Van Reusel,** Clinical Data Interchange Standards Consortium
- **Christopher Chute,** Johns Hopkins University
- **Robert Califf,** Duke University

4:30 p.m. **Closing Remarks and Adjournment**

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