U.S. FOOD & DRUG ADMINISTRATION

Center for Drug Evaluation and Research (CDER)/Center for Biologic Evaluation and Research (CBER)

Public Meeting on Promoting the Use of Complex Innovative Designs in Clinical Trials
FDA Great Room, Building 31, Room 1503
10903 New Hampshire Avenue, Silver Spring, MD 20993-0002

March 20, 2018

AGENDA

Meeting Website: https://www.fda.gov/Drugs/NewsEvents/ucm587344.htm
Docket No. FDA-2018-N-0049

8:30 a.m. **Welcome, Opening Remarks, and Panel Introductions**
Aloka Chakravarty, U.S. Food and Drug Administration

8:45 a.m. **Session I: General Considerations for Complex Adaptive Clinical Trial Designs to Support the Effectiveness and Safety of Drugs or Biologics**
Moderator: Dionne L. Price, U.S. Food and Drug Administration

Presentation: *Gregory Levin, U.S. Food and Drug Administration (15 mins)*
Primary Discussant(s): *Frank Bretz, Novartis and Scott S. Emerson, University of Washington (10 mins)*
Panel Discussion *(50 mins)*
Audience Q&A *(15 mins)*

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

10:30 a.m. **Session II: General Considerations for Other Innovative Designs Including External/Historical Control Subjects, Bayesian Designs, and Master Protocols**
Moderator: Dionne L. Price, U.S. Food and Drug Administration

Presentation: *Lisa LaVange, University of North Carolina (15 mins)*
Primary Discussant(s): *Roger J. Lewis, University of California, Los Angeles, and Berry Consultants, LLC and Frank E Harrell Jr, Vanderbilt University and the U.S. Food and Drug Administration (10 mins)*
Panel Discussion *(50 mins)*
Audience Q&A *(15 mins)*

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

1:00 p.m. **Session III: Clinical Trial Simulations for Confirmatory Trial Design and Planning**
Moderator: Dionne L. Price, U.S. Food and Drug Administration

Presentation: *John Scott, U.S. Food and Drug Administration (15 mins)*

Primary Discussant(s): *Scott Berry, Berry Consultants, LLC, Cyrus R. Mehta, Cytel Inc, and Karen Lynn Price, Eli Lilly and Company (15 mins)*
Panel Discussion *(45 mins)*
Audience Q&A *(15 mins)*

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

2:45 p.m. **Session IV: Complex Innovative Design Pilot Program**
Moderator: Dionne L. Price, U.S. Food and Drug Administration

Presentation: *Dionne L. Price, U.S. Food and Drug Administration (15 mins)*
Primary Discussant(s): *Gracie Lieberman, Genentech and Z. John Zhong, Biogen (10 mins)*
Panel Discussion *(50 mins)*
Audience Q&A *(15 mins)*

4:15 p.m. **Closing Remarks**
Dionne L. Price, U.S. Food and Drug Administration

4:30 p.m. **Adjournment**

Panelists who will participate in all sessions:
Deborah Ashby, PhD, Imperial College London
Scott Berry, PhD, Berry Consultants, LLC
Frank Bretz, PhD, Novartis
Ivan S.F. Chan, PhD, AbbVie
Scott S. Emerson, MD, PhD, University of Washington
Steven Goodman, MD, PhD, Stanford University
Frank E Harrell Jr, PhD, Vanderbilt University and U.S. Food and Drug Administration
Lisa LaVange, PhD, University of North Carolina
J. Jack Lee, MD, MS, DDS, University of Texas MD Anderson Cancer Center
Roger J. Lewis, MD, PhD, University of California, Los Angeles and Berry Consultants, LLC
Gracie Lieberman, MS, Genentech
Olga V. Marchenko, PhD, Bayer
Cyrus R. Mehta, PhD, Cytel Inc
William J. Meurer, MD, MS, University of Michigan
Karen Lynn Price, PhD, Eli Lilly and Company
Z. John Zhong, PhD, Biogen

U.S. Food and Drug Administration panel participants, by session:
Session I: Shein-Chung Chow, PhD, John Scott, PhD, Gregory Levin, PhD, Joseph G. Toerner, MD, MPH
Session II: Julie Beitz, MD, Rajeshwari Sridhara, PhD
Session III: Telba Irony, PhD, Gregory Levin, PhD, Thomas Permutt, PhD, John Scott, PhD
Session IV: Julie Beitz, MD, Laura Lee Johnson, PhD, Stefanie Kraus, JD, MPH