



PDUFA VII Public Meeting on Best Practices for Meeting Management

Monday, July 22, 2024

8:30 a.m. **In-Person Sign-In and Coffee**

9:00 a.m. **Opening Remarks and Welcome**

Danielle Villata, Center for Drug Evaluation and Research, FDA
Program Evaluation and Implementation Staff, Office of Strategic Programs

9:05 a.m. **Introduction to Moderator and Panelists**

Valerie Overton, Eastern Research Group Inc.
Vice President, Meeting Moderator

Jennifer L. Mercier, Center for Drug Evaluation and Research, FDA
Office Director of Office of Regulatory Operations, Office of New Drugs

Banu Karimi-Shah, Center for Drug Evaluation and Research, FDA
Deputy Division Director of Division of Pulmonology, Allergy, and Critical Care, Office of Immunology and Inflammation, Office of New Drugs

Pamela K. Lucarelli, Center for Drug Evaluation and Research, FDA
Division Director of Division of Regulatory Operations for Rare Diseases, Pediatrics, Urologic, and Reproductive Medicine, Office of Regulatory Operations, Office of New Drugs

Sonday Kelly, Center for Biologics Evaluation and Research, FDA
Division Director of Division of Regulatory Operations and Program, Office of Regulatory Operations

Ramani Sista, Center for Biologics Evaluation and Research, FDA
Office Director of Office of Review Management and Regulatory Review, Office of Therapeutic Products

Alex May, CSL Behring
North America Lead – Regulatory Science, Policy, & Intelligence

Brad Jordan, Eli Lilly and Company
Associate Vice President, Regulatory Policy and Strategy

Alison Maloney, Bayer
Head & VP Regulatory Affairs North America



Liza O'Dowd, Johnson & Johnson
*VP, Global Regulatory Affairs, Immunology, Global Policy & Regulatory Intelligence,
and North American Liaison, Janssen Inc*

- 9:10 a.m. **Overview of PDUFA Meeting Metrics**
J. Paul Phillips, Center for Drug Evaluation and Research, FDA
Director of Office of Program Operation, Office of New Drugs
- 9:55 a.m. **Panel Discussion 1:** General Purpose and Objective of FDA-Sponsor Meetings
- 10:20 a.m. **Break**
- 10:40 a.m. **Panel Discussion 2:** Meeting Requests and Background Packages
- 11:05 a.m. **Panel Discussion 3:** Meeting Management for All Meeting Types
- 11:30 a.m. **Panel Discussion 4:** Meeting Minutes and Follow-Up Opportunities
- 11:55 a.m. **Lunch Break**
- 12:35 p.m. **Panel Discussion 5:** In-Person and Virtual Face-to-Face Meetings
- 1:00 p.m. **Panel Discussion 6:** INTERACT and Type D Meetings
- 1:25 p.m. **Summary and Concluding Remarks**
Valerie Overton, Eastern Research Group Inc.
Vice President, Meeting Moderator
- 1:30 p.m. **Open Public Comments**