



**Center for Drug Evaluation and Research (CDER)/Center for Biologics Evaluation and Research (CBER)**

Public Workshop on Advancing the Use of Complex Innovative Designs in Clinical  
Trials: From Pilot to Practice  
FDA Great Room, Building 31,  
10903 New Hampshire Avenue, Silver Spring, MD 20993-0002

March 5, 2024

**AGENDA**

**Meeting Website:** <https://www.fda.gov/news-events/advancing-use-complex-innovative-designs-clinical-trials-pilot-practice-03052024>

**Docket No.** [FDA-2023-N-4965](https://www.fda.gov/oc/foia/docket-03052024)

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- 9:00 a.m.**      **Welcome, Opening Remarks, and Panel Introductions**  
*Dr. John Scott, U.S. Food and Drug Administration*
- 9:15 a.m.**      **Session I: Speaker Presentation, “The Chilled Platelet Study (CHIPS): An Adaptive, Storage-Duration Finding Trial” – Dr. Roger J. Lewis**  
**Presentation:** *Dr. Roger J. Lewis, University of California, Los Angeles and Berry Consultants, LLC (30 mins)*  
**Panel Discussion (10 mins)**  
*Moderator: Dr. John Scott, U.S. Food and Drug Administration*
- 9:55 a.m.**      **Session II: Speaker Presentation, “Advancing Innovation: A Master Protocol for Patients with Chronic Pain” – Dr. Karen Lynn Price**  
**Presentation:** *Dr. Karen Lynn Price, Eli Lilly and Company (30 mins)*  
**Panel Discussion (10 mins)**  
*Moderator: Dr. John Scott, U.S. Food and Drug Administration*
- 10:35 a.m.**      **Break (15 mins)**
- 10:50 a.m.**      **Session III: Speaker Presentation, “A Case Study of a Hybrid Control Design in Diffuse B-Cell Lymphoma” – Dr. Herbert (Herb) Pang**  
**Presentation:** *Dr. Herbert (Herb) Pang, Genentech/Roche (30 mins)*  
**Panel Discussion (10 mins)**  
*Moderator: Dr. John Scott, U.S. Food and Drug Administration*
- 11:30 a.m.**      **Lunch (60 mins)**
- 12:30 p.m.**      **Panel Discussions (120 mins)**



- 2:30 p.m.**      **Break** *(15 mins)*
- 2:45 p.m.**      **In-Person and Online Q&A** *(35 mins)*
- 3:20 p.m.**      **Closing Remarks**  
*Dr. John Scott, U.S. Food and Drug Administration*
- 3:30 p.m.**      **Adjournment**

**Panelists:**

*Frank Bretz, PhD, Novartis*

*Dean Follmann, PhD, National Institute of Allergy and Infectious Diseases*

*Frank E Harrell, PhD, Vanderbilt University and U.S. Food and Drug Administration*

*Rebecca Hubbard, PhD, University of Pennsylvania*

*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*

*Herbert (Herb) Pang, PhD, Genentech/Roche*

*Karen Lynn Price, PhD, Eli Lilly and Company*

*Stephen Ruberg, PhD, Analytix Thinking*