



NHLBI Biostatistics Workshop on Clinical Trial Designs: Innovative Endpoints and Futility Monitoring

Monday-Tuesday, September 18-19, 2023

Location

45 Ruth L. Kirschstein Auditorium, Building 45,
Natcher Conference Center, NIH Campus, Bethesda, MD 20892

Program

Day 1: Monday, September 18

7:30am-8:05am Registration
8:05am-8:10am Welcome from OBR Director: Nancy L. Geller, PhD

Sessions 1-3 Endpoint Choices in Clinical Trials

8:10am-10:00am **Session 1: Statistical Methods for Endpoint Choices**
Chair: Colin Wu NHLBI/NIH
 8:10am-8:35am Laura Lee Johnson FDA
 8:35am-9:00am LJ Wei Harvard U.
 9:00am-9:25am Scott Evans George Washington U.
 9:25am-9:50am Richard Cook U Waterloo
 9:50am-10:00am Q&A, Floor Discussion

10:00am-10:10am **Break**

10:10am-12:00am **Session 2: Endpoints in Cardiovascular Diseases**
Chair: Eric Leifer NHLBI/NIH
 10:10am-10:35am Phillip Yang Stanford U.
 10:35am-11:00am James Troendle NHLBI/NIH
 11:00am-11:25am Tianxi Cai Harvard U.
 11:25am-11:50am Song Yang NHLBI/NIH
 11:50am-12:00pm Q&A, Floor Discussion

12:00pm-1:10pm **Break**

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1:10pm-3:00pm **Session 3: Endpoints in Blood and Lung Diseases**

Chair:	Xin Tian	NHLBI/NIH
1:10pm-1:35pm	Neal S. Young	NHLBI/NIH
1:35pm-2:00pm	Anna Bellach	NHLBI/NIH
2:00pm-2:25pm	Ying Lu	Stanford U
2:25pm-2:50pm	Joseph Cappelleri	Pfizer Inc.
2:50pm-3:00pm	Q&A, Floor Discussion	

3:00pm-3:10pm **Break**

Sessions 4-6 **Innovative Trial Monitoring Methods**

3:10pm-5:00pm **Session 4: Statistical Methods for Logistics of Futility Monitoring**

Chair:	Neal Jeffries	NHLBI/NIH
3:10pm-3:35pm	Dong-Yun Kim	NHLBI/NIH
3:35pm-4:00pm	Daniel F. Heitjan	Southern Methodist U.
4:00pm-4:25pm	Yajun Mei	Georgia Tech
4:25pm-4:50pm	Yanhong Wu	Cal State U.
4:50pm-5:00pm	Q&A, Floor Discussion	

Day 2: Tuesday, September 19

8:00am-9:50am **Session 5: Statistical Methods for Futility Monitoring**

Chair:	Jungnam Joo	NHLBI/NIH
8:00am-8:25am	Mike Proschan	NIAID/NIH
8:25am-8:50am	Christopher Jennison	Bath University
8:50am-9:15am	Scott Berry	Berry Consultant, LLC
9:15am-9:40am	Karen Higgins	FDA
9:40am-9:50am	Q&A, Floor discussion	

9:50am-10:00am **Break**

10:00am-11:50am **Session 6: Case Studies for Futility Monitoring**

Chair:	Mario Stylianou	NHLBI/NIH
10:00am-10:25am	Chris Lindsell	Duke U
10:25am-10:50am	Vlad Dragalin	Johnson & Johnson
10:50am-11:15am	Erica H. Brittain	NIAID/NIH
11:15am-11:40am	Wesley Self	Vanderbilt U.
11:40am-11:50pm	Q&A, Floor Discussion	

2023 NHLBI BIOSTATISTICS WORKSHOP

11:50am-noon

Break

Noon-1:00pm

Panel Discussion, Summary & Recommendations to NHLBI

Chair:

Nancy L. Geller

NHLBI/NIH

Panelists:

Joseph Cappelleri

Pfizer Inc.

Vlad Dragalin

Johnson & Johnson

Scott Evans

The George Washington University

Karen Higgins

FDA

Dong-Yun Kim

NHLBI

Chris Lindsell

Duke U.

Mike Proschan

NIAID

James Troendle

NHLBI

Lee-Jen Wei

Harvard University

Colin Wu

NHLBI

Neal Young

NHLBI

1:00pm

Adjourn