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 (September 18, Monday)

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

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

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 (September 19, Tuesday)

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

10:10am-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
11:50am-noon  Break

noon-1:00pm  Panel Discussion, Summary & Recommendations to NHLBI
Chair: Nancy L. Geller  NHLBI/NIH
Panelist: TBA

1:00pm  Adjourn