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
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
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