## **Biostatistics**

Center for Clinical Epidemiology & Biostatistics (CCEB)



9th Annual Clinical Trials Conference

# University of Pennsylvania Center for Clinical Epidemiology and Biostatistics Department of Biostatistics and Epidemiology

9th Annual Conference on Statistical Issues in Clinical Trials

April 13, 2016

# Where Are We with Adaptive Clinical Trial Designs?



Arthur H. Rubenstein Auditorium Smilow Center for Translational Research (SCTR)

Perelman School of Medicine University of Pennsylvania 3400 Civic Center Boulevard Philadelphia, PA 19104 The 2016 Conference will bring together leading scientists who will discuss current statistical issues in adaptive trial designs. Participants from all sectors with an interest in clinical trials methodology are encouraged to register.

### Funding Co-Sponsors:

University of Pennsylvania Center Clinical Epidemiology and Biostatistics & the Department of
Biostatistics and Epidemiology
Genentech (A Member of the Roche Group)
Johnson & Johnson (Janssen R&D)
Merck

#### Co-Sponsors:

American Statistical Association - 2016 Annual Meeting Information Society for Clinical Trials - 2016 Annual Meeting Information

Faculty	Institution	Topic (Click for Slide Sets.)
Frank Bretz, PhD	Novartis Pharmaceuticals	Adaptive Designs: The Swiss Army Knife
		Among Clinical Trial Designs?
Lisa LaVange, PhD	FDA	Adaptive Trial Designs and the FDA
Mahesh Parmar	University College London	Improving Outcomes for Patients As
		Rapidly As Possible: Some New Designs
		for Phase III Trials
Michael Proschan, PhD	NIAID	Blinded Adaptations: What Is and Is Not
		Okay?
Peter F. Thall, PhD	MD Anderson Cancer Center	r Caveats for Outcome-Adaptive
		Randomization in Comparative Clinical
		Trials
Bruce W. Turnbull, PhD	Cornell University	Adaptive Trial Designs: A DSMB
	,	Perspective

Panelists (Click institution for slide sets.)

Rick Chappell, PhD University of Wisconsin-Madison

Jason T. Connor, PhD Berry Consultants

Angie DeMichele, MD, University of Pennsylvania

MSCE

Valerie Durkalski, PhD Medical University of South

Carolina

Steven Joffe, MD, MPH
Janet Wittes, PhD

University of Pennsylvania
Statistics Collaborative, Inc.

#### Program:

A current version of the program can be found HERE.

#### Venue:

The Conference will be held in the Arthur H. Rubenstein Auditorium at the Smilow Center for Translational Research on the campus of the University of Pennsylvania Perelman School of Medicine. A campus map can be found here.

#### **Event Day Parking:**

Day parking for the event can be purchased in advance for a \$20 fee. Event day parking will be located at the Curie Garage, 426 Curie Boulevard on Penn's campus. To secure a space, please indicate you would like parking during online registration. A map of Curie Garage and conference location can be viewed here. Conference attendees staying overnight should contact their hotel for overnight parking information. Sheraton University City overnight parking information can be found here.

#### Lodging:

The Sheraton University City is located within easy walking distance of the conference. A limited number of rooms have been secured at Sheraton University City at the discounted rate of \$189. You may also make reservations by phone (1-888-627-7071) referencing "Statistical Issues in Clinical Trials" for the discount. The cut-off date for booking at the reduced rate is **March 28, 2016**. Many alternative hotels in Center City Philadelphia are also a short distance from the UPenn campus. Participants are encouraged to make their housing arrangements as soon as possible.

Registration and Fees: CONFERENCE SOLD OUT - REGISTRATION CLOSED

For additional information, contact: Jonas H. Ellenberg Ph.D., Emeritus Professor of Biostatistics Email: jellenbe@upenn.edu

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## 9<sup>th</sup> Annual Conference on Statistical Issues in Clinical Trials

# Center for Clinical Epidemiology and Biostatistics, UPENN April 13, 2016

# Arthur H. Rubenstein Auditorium Smilow Center for Translational Research (SCTR)

# **Current Issues Regarding the use of Adaptive Designs in Clinical Trials**

Current Issues	PRESENTERS		
8:00 a.m. – 8:30 a.m.	BREAKFAST		
8:30 a.m. – 8:40 a.m.	Opening Remarks and Logistics Jonathan A. Epstein MD , University of Pennsylvania		
	Moderator: Andrea Troxel, University of Pennsylvania		
8:40 a.m. – 9:05 a.m.	Frank Bretz, PhD, Novartis Pharmaceuticals  Adaptive Designs: The Swiss Army Knife Among Clinical Trial Designs?		
9:05 a.m. – 9:30 a.m.	Michael Proschan, PhD, NIAID  Blinded Adaptations: What Is and Is Not Okay?		
9:30 a.m. – 9:55 a.m.	Peter F. Thall, PhD, MD Anderson Cancer Center Caveats for Outcome-Adaptive Randomization in Comparative Clinical Trials		
9:55 a.m. – 10:20 a.m.	BREAK		
10:20 a.m. – 11:15 a.m.	Discussion panel: Valerie Durkalski, PhD, Medical University of South Carolina Steven Joffe, MD, MPH, University of Pennsylvania Rick Chappell, PhD, University of Wisconsin-Madison		
11:15 a.m. – 11:35 a.m.	OPEN FORUM		
11:35 a.m. – 12:55 p.m.	LUNCH		
·	Moderator: Pamela Shaw, University of Pennsylvania		
12:55 p.m. – 1:20 p.m.	Mahesh Parmar, DPhil, University College London Improving Outcomes for Patients As Rapidly As Possible: Some New Designs for Phase III Trials		
1:20 p.m. – 1:45 p.m.	Bruce W. Turnbull, PhD, Cornell University  Adaptive Trial Designs: A DSMB Perspective		
1:45 p.m. – 2:10 p.m.	Lisa LaVange, PhD, FDA  Adaptive Trial Designs and the FDA		
2:10 p.m. – 2:35 p.m.	BREAK		
2:35 p.m. – 3:25 p.m.	Discussion panel:  Janet Wittes, PhD, Statistics Collaborative, Inc.  Angie DeMichele, MD, MSCE, University of Pennsylvania  Jason T. Connor, PhD, Berry Consultants		
3:25 p.m. – 3:45 p.m.	OPEN FORUM		
3:45 p.m. – 4:00 p.m.	CLOSING REMARKS: Susan Ellenberg, University of Pennsylvania		

