



**10<sup>th</sup> Annual Conference on Statistical Issues in Clinical Trials**  
**Center for Clinical Epidemiology and Biostatistics, UPENN**  
**April 19, 2017**  
**Arthur H. Rubenstein Auditorium**  
**Smilow Center for Translational Research (SCTR)**

**Current Issues Regarding Data and Safety Monitoring Committees in Clinical Trials**  
**Tentative Program**

APPROXIMATE TIME	PRESENTERS
8:00 a.m. – 8:30 a.m.	<b>BREAKFAST</b>
8:30 a.m. – 8:40 a.m.	<b>Opening Remarks:</b> Ezekiel Emanuel, MD, PhD, University of Pennsylvania <b>Logistics:</b> Susan Ellenberg, PhD, University of Pennsylvania
	<b>Moderator:</b> James Lewis, MD, MSCE, University of Pennsylvania
8:40 a.m. – 9:05 a.m.	Thomas Fleming, PhD, University of Washington <i>Emerging Challenges in the Practice of Clinical Trial Data Monitoring Committees</i>
9:05 a.m. – 9:35 a.m.	<b>Discussion panel:</b> Barry Davis, MD, PhD, University of Texas Steven Snapinn, PhD, Amgen Maureen Maguire, PhD, University of Pennsylvania
9:35 a.m. – 10:05 a.m.	<b>OPEN FORUM</b>
10:05 a.m. – 10:30 a.m.	<b>BREAK</b>
10:30 a.m. – 10:55 a.m.	David DeMets, PhD, University of Wisconsin <i>The Independent Statistician Model: How Well it is Working?</i>
10:55 a.m. – 11:25 a.m.	<b>Discussion panel:</b> Janet Wittes, PhD, Statistics Collaborative, Inc. Corsee Sanders, PhD, Juno Therapeutics David Kerr, MS, Axio Research
11:25 a.m. – 11:55 a.m.	<b>OPEN FORUM</b>
11:55 a.m. – 1:05 p.m.	<b>LUNCH</b>
	<b>Moderator:</b> Alisa Stephens-Shields, PhD, University of Pennsylvania
1:05 p.m. – 1:30 p.m.	Pamela Shaw, PhD, University of Pennsylvania <i>Choosing Monitoring Boundaries: Balancing Risks and Benefits</i>
1:30 p.m. – 2:00 p.m.	<b>Discussion panel:</b> John Lachin, ScD, George Washington University Kay Dickersin, PhD, Johns Hopkins University Dennis Dixon, PhD, National Institute of Allergy & Infectious Diseases, NIH (retired)
2:00 p.m. – 2:30 p.m.	<b>OPEN FORUM</b>
2:30 p.m. – 2:55 p.m.	<b>BREAK</b>
2:55 p.m. – 3:20 p.m.	James Neaton, PhD, University of Minnesota <i>How to Construct an Optimal Interim Report: What the DMC Does and Doesn't Need to Know</i>
3:20 p.m. – 3:50 p.m.	<b>Discussion panel:</b> Frederick Ferris, MD, National Eye Institute, NIH Stephen Kimmell, MD, MSCE, University of Pennsylvania Judith Goldberg, ScD, New York University
3:50 p.m. – 4:20 p.m.	<b>OPEN FORUM</b>
4:20 p.m. – 4:35 p.m.	<b>CLOSING REMARKS:</b> Susan Ellenberg PhD, University of Pennsylvania