

11th Annual Conference on Statistical Issues in Clinical Trials Center for Clinical Epidemiology and Biostatistics, U Penn

April 18, 2018 Arthur H. Rubenstein Auditorium Smilow Center for Translational Research (SCTR)

Estimands, Missing Data and Sensitivity Analysis

	PRESENTERS
7:45 a.m. – 8:45 a.m.	REGISTRATION, BREAKFAST AND AV PREPARATION
8:45 a.m. – 9:00 a.m.	Opening Remarks/Logistics: Susan S. Ellenberg, PhD, University of Pennsylvania
	AM MODERATOR: Pamela A. Shaw, PhD, University of Pennsylvania
9:00 a.m. – 9:30 a.m.	DEVAN V. MEHROTRA, PhD , Merck Research Laboratories and University of Pennsylvania ICH Guidance on Estimands and Sensitivity Analysis: Why and what?
9:30 a.m. – 10:00 a.m.	THOMAS PERMUTT, PhD , US Food and Drug Administration, CDER A regulatory perspective on defining treatment effects
10:00a.m 10:30 a.m.	BREAK
10:30-11:15 a.m.	Discussion panel 1: FRANK W. ROCKHOLD, PhD, Duke University, DCRI ANNE LINDBLAD, PhD, EMMES Corporation JAY P. SIEGEL, MD, Janssen (ret.) GEERT MOLENBERGHS, PhD, Universiteit Hasselt and KU Leuven
11:15 a.m. – 12:00 p.m.	OPEN FORUM
12:00 p.m. – 1:00 p.m.	LUNCH
	PM MODERATOR: Mary E. Putt, PhD, ScD, University of Pennsylvania
1:00 p.m. – 1:30 p.m.	JOSEPH G. IBRAHIM, PhD, UNC, Gillings School of Public Health Quantifying the average of the time-varying Hazard Ratio via a class of transformations
1:30 p.m. – 2:00 p.m.	SCOTT S. EMERSON, MD, PhD, University of Washington Analyzing Sensitivity to Data Missing Not At Random (MNAR): A Framework for Design, Analysis, and Reporting Professor of Biostatistics
2:00 p.m. – 2:30 p.m.	DANIEL O. SCHARFSTEIN, ScD, Johns Hopkins Bloomberg School of Public Health A Causal Inference Perspective on the Proposed ICH-E9 Addendum.
2:30 p.m. –3:00 p.m.	BREAK
3:00 p.m. – 3:45 p.m.	Discussion panel 2: RODERICK J LITTLE, PhD, University of Michigan School of Public Health ERIC J. TCHETGEN TCHETGEN, PhD, Wharton School, University of Pennsylvania ANDREA B. TROXEL, ScD, New York University Langone Health
3:45 p.m. – 4:25 p.m.	OPEN FORUM