

University of Pennsylvania Annual Conference on
Statistical Issues in Clinical Trials: From Bench to Bedside to Community
April 18, 2008

Topic for 2008 Conference
Early, Translational and Proof of Concept Studies:
The "Go/No Go" Decisions

TENTATIVE PROGRAM

Time Slot	Speaker	Institution	Topic
08:00-08:30	BREAKFAST		
08:30-08:45	Susan Ellenberg, PhD Arthur H. Rubenstein, MBBCh Dean of School of Medicine	Univ PA	Welcome, Introductions and Goals
SESSION 1: Early and Translational Studies			
08:45-09:05	Janet Woodcock, MD	FDA	Early decision-making & FDA Critical Path
09:05-09:25	Garret FitzGerald, MD	Univ PA	Translational research and CTSA
09:25-09:50	Stephen Senn, PhD	Glasgow Univ	Pharmaceutical Industry Prioritization
09:50-10:10	Open Forum		
10:10-10:30	BREAK		
SESSION 2: Early Phase Trial Designs			
10:30-10:55	Lawrence Rubinstein, PhD	NCI	Phase 0 Trials
10:55-11:20	Peter Thall, PhD	MD Anderson	Multidimensional treatment effects
11:20-11:45	Daniel Sargent, PhD	Mayo Clinic	Optimal dose for efficacy & toxicity
11:45-12:15	Open Forum		
12:15-01:30	LUNCH		
SESSION 3: Decision-making and Proof of Concept Trials			
01:30-01:55	Donald Berry, PhD	MD Anderson	Statistical Science & Decision-making
01:55-02:20	Lawrence Gould, PhD	Merck	Futility/Proof of concept
02:20-02:45	Peter Gilbert, PhD	Univ Washington	Proof of concept trials
02:45-03:15	Open Forum		
03:15-03:45	BREAK		
SESSION 4: Panel Discussion			
03:45-04:45	Jonas Ellenberg, PhD, moderator Donald Berry, PhD Marie Davidian, PhD Frank Rockhold, PhD Janet Wittes, PhD	Univ PA MD Anderson NC State Univ GlaxoSmithKline Stat Collab Inc.	New remarks (5-10 min) by each panelist, then Panel Discussion and Open Forum
04:45-05:00	Jonas Ellenberg, PhD	Univ PA	Closing Remarks, participants complete feedback forms