

## Pre-Symposium Conference for Innovative Designs of Clinical Trials and Related Topics

June 19-20, 2009, Freidenrich Auditorium, Lucile Packard Children's Hospital, Stanford University

---

Time	Speaker	Affiliation	Talk title
<b>Friday, June 19</b>			
9:15	Philip Lavori	Stanford	Opening remarks
<b>Session I (Chair: Richard Olshen)</b>			
9:20	Robert Negrin	Stanford	Regulatory T cells from the bench to the clinic
10:00	Sandy Srinivas	Stanford	Challenges in clinical trial designs in prostate cancer
10:40	Tyler Martin	Dynavax	Innovative and accelerated development of an improved therapeutic for cystic fibrosis: Tobramycin inhalation powder
11:20	Philip Lavori	Stanford	Discussant
12:00	Lunch		
<b>Session II (Chair: Corry Dekker)</b>			
1:50	Anne-Marie Duliege	Affymatrix	Safety assessment during the development of new drugs: new challenges and statistical considerations
2:30	Joseph Heyse	Merck	Application of sequential stopping boundaries in vaccine safety trials
3:10	Bruce Fireman	Kaiser Permanente	Exact sequential analysis for vaccine safety surveillance
3:50	Break		
<b>Session III (Chair: Philip Lavori)</b>			
4:00	John Rush	NUS/Duke	Why not study representative patients and likely treatment strategies during antidepressant drug development
4:40	Balasubramanian Narasimhan	Stanford	Statistical software for designing Phase I/II cancer studies
<b>Saturday, June 20</b>			
<b>Session IV (Chair: Ying Lu)</b>			
8:15	Sue-Jane Wang	FDA	How might adaptive design be useful to learn biomarker predictivity versus to test treatment effect potentially predicted by genomic biomarker classifier?
8:55	Ray Zhu	Eisai	Using regret concept in planning of clinical development of new drugs
9:35	Mei-Chiung Shih	Stanford	A strategic approach to designing Phase II cancer studies
10:15	Break		
<b>Session V (Chair: Mei-Chiung Shih)</b>			
10:30	Janet Wittes	Statistics Collaborative	Adaptive designs: Gaming the system

---

---

11:10	Gordon Lan	Johnson & Johnson	The use of conditional power and predictive power in clinical trials
11:50	Eric Holmgren	Genentech	Extending a study beyond its "final" analysis
12:30	Lunch		

**Section VI (Panel Discussion)**

1:30-3:00	Emerging statistical issues in the design and analysis of clinical trials		
	Dan Anbar	DANA Pharmaceutical Consulting	
	Agnes Hsiung	NHRI	
	Tze Leung Lai	Stanford	

---