



STANFORD

SCHOOL OF MEDICINE

Stanford University Medical Center

Conference for Innovative Designs of Clinical Trials and Related Topics

June 19-20, 2009

FREIDENRICH AUDITORIUM

LUCILE PACKARD CHILDREN'S HOSPITAL, STANFORD UNIVERSITY

(For registration, please goto: <http://hrp.stanford.edu/conferences/IDCT.html>

or email: bchung@stanford.edu)

June 19, 2009 (Friday)

09:15 Philip Lavori, Stanford Opening remarks

Session I (Chair: Richard Olshen)

09:20	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	Effectiveness Experiments: challenges and new directions

Session II (Chair: Corry Dekker)

01:50	Anne-Marie Duliege, Affymax	Safety assessment during the development of new drugs: new challenges and statistical considerations
02:30	Joseph Heyse, Merck	Application of sequential stopping boundaries in vaccine safety trials
03:10	Bruce Fireman, Kaiser Permanente	Influenza vaccination and mortality: a novel approach to differentiating vaccine effects from bias

Session III (Chair: Philip Lavori)

04:00	Corry Dekker, Stanford	Influenza A/H1N1 (Swine flu)
04:40	Balasubramanian Narasimhan, Stanford	Statistical software for designing Phase I/II cancer studies

June 20, 2009 (Saturday)

Session IV (Chair: Ying Lu)

08:15	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?
08:55	Ray Zhu, Eisai	Using regret concept in planning of clinical development of new drugs
09:35	Mei-Chiung Shih, Stanford	A strategic approach to designing Phase II cancer studies

Session V (Chair: Mei-Chiung Shih)

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

Session VI (Panel Discussion)

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