

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>)

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 Exact sequential analysis for vaccine safety surveillance

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