

The
University of Michigan
Department of Biostatistics

Presents

J. Jack Lee

Speaking On:

**Biomarker Based Adaptive Designs for Targeted Agent
Development - A Step Toward Personalized Medicine**

Advances in biomedicine have revolutionized cancer therapy by the development of targeted agents. Targeted therapies have shown to be more efficacious and less toxic than the conventional broad-based chemotherapies. Targeted therapies, however, do not work for all patients. One major challenge is to identify markers to predict treatment efficacy. We propose biomarker based adaptive designs to (1) identify prognostic and predictive markers for targeted agents, (2) to test treatment efficacy, and (3) to provide better treatments for patients enrolled in the trial. In contrast to the frequentist equal randomization designs, Bayesian adaptive randomization designs allow treating more patients with effective treatments, monitoring the trial more frequently to stop ineffective treatments early, and increasing efficiency while controlling type I and type II errors. Bayesian logistic regression and Cox regression are applied for binary and time-to-event endpoints. Putative markers are chosen via variable selection methods. The proposed design can be more efficient, more ethical, and more flexible in the study conduct than standard designs. Examples and experiences learned from real studies will be given.

Thursday, October 15, 2009
3:30 p.m. – Room M1152, SPH II

Coffee and Cookies will be served for seminar guests at
3:00 p.m. in SPH II, Room M4034