IMPACT: Innovative Methods Program for Advancing Clinical Trials

1st Annual Symposium:

"New Paradigms in Clinical Trials Methodology"

8:00-8:30AM Continental Breakfast

8:30-8:40AM Welcome

8:40-9:35AM Session I: "Biomarkers and Trial Design"
Ed Korn, NCI, *"Biomarker-adaptive clinical trial designs"*
Xiaofei Wang, Duke, *"Biased sampling and its applications in biomarker validation"*

9:35-10:30AM Session II: "Pharmacogenetic/Pharmacogenomic Analysis"
Jung-Ying Tzeng, NC State, *"A gene-trait similarity regression method for gene-level pharmacogenetics analysis"*
Todd Auman, UNC, *"Pharmacogenomic interrogation of colorectal cancer using next-generation whole exome sequencing"*

10:30-10:45AM Break

10:45AM-12:30PM Session III: "Design and Analysis Involving Complex Time-to-event Data"
Jason Fine, UNC, *"An overview of competing risks data, with applications in clinical trials"*
Zhiguo Li, Duke, *"Fitting Cox models with doubly censored data using spline-based marginal likelihood"*
Donglin Zeng, UNC, *"Estimating treatment effects with treatment switching via semi-competing risks models: An application to a colorectal cancer study"*
Liddy Chen, UNC, *"Design consideration for complex survival models"*

12:30-1:40PM Lunch

1:40-2:35PM Session IV: "Adaptive Trial Design"
H.M. James Hung, FDA, *"Utilities and challenges of adaptive designs in drug development"*
Giovanni Parmigiani, Harvard, *"Adaptive randomized design for patients with recurrent glioblastoma"*

2:35-2:55PM Break

2:55-3:50PM Session V: "Assessment of Drug Safety"
Mark Levenson, FDA, *"Safety decision-making with multiple sources and different types of studies—recent examples from FDA Advisory Committees"*
David Madigan, Columbia, *"Drug safety in spontaneous reports, observational databases, and clinical trials: Can we do better?"*

3:50-4:10PM Break

4:10-5:30PM Session VI "Statistical Methods for Discovery of Individualized Treatment"
Marie Davidian, NC State, *"A robust method for estimating optimal treatment regimes"*
Yingqi Zhao, UNC, *"Outcome weighted learning for selecting individualized treatment regimens"*
Eric Laber, NC State, *"Adaptive inference after model selection"*

5:30PM Adjourn

Thursday November 17, 2011   Sheraton Imperial Hotel   Durham, NC