

THE UNIVERSITY OF GEORGIA



DEPARTMENT OF STATISTICS

FRANKLIN COLLEGE OF ARTS AND SCIENCES

The University of Georgia  
Department of Statistics

# Colloquium Series

Yan Daniel Zhao

Department of Biostatistics and Epidemiology  
University of Oklahoma Health Sciences Center  
at Tulsa

## “Design and Analysis Considerations in Clinical Trials With a Sensitive Subpopulation ”

We present research on clinical trials with a sensitive subpopulation of patients, that is, a subgroup that is more likely to benefit from the treatment than the overall population. Given a sensitive subgroup defined by a prespecified classifier, for example, a clinical marker or pharmacogenomic marker, the trial's outcome is declared positive if the treatment effect is established in the overall population or in the subgroup. We provide a summary of key considerations in clinical trials with a sensitive subgroup, including multiplicity and enrichment adjustments as well as optimality considerations in the analysis strategy. The methodology proposed in this article is illustrated using a neuroscience clinical trial and its operating characteristics are accessed via a simulation study.

Key Words: Clinical trials; Enriched clinical trials; Sensitive population; Type I error rate control; Weighted power.

For more information,  
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Thursday, December 1st, 2011

3:30 PM at 306 Statistics Building

Refreshments will be immediately after the talk in The  
Cohen Room, room 230, Statistics Building