THE UNIVERSITY OF GEORGIA
DEPARTMENT OF STATISTICS

Colloquium Series

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3:30pm in room 102, Caldwell Building

On the Use of Co-Data in Clinical Trial

Historical data are important for the design of a clinical trial. Yet these data are rarely used in the analysis of the actual trial. While justifiable in certain situations, ignoring historical data can lead to less accurate inferences, and, therefore, suboptimal decisions. One primary concern of using historical data in clinical trial design and analysis is possible prior-data conflict. We propose a robust Bayesian meta-analytic approach to alleviate this issue. This approach has encouraged better and more frequent use of historical data in clinical trials and widely used in industry. Furthermore, the framework is extended to co-data, which comprise all relevant (historical and concurrent) trial-external data. These data can be used for the inference of the parameter in the actual trial via meta-analytic approaches. While the use of co-data in clinical trials is attractive, it is also ambitious. For example, avoiding undue weight of co-data (relative to actual trial data) is important, which can often be achieved by plausible assumptions about between-trial heterogeneity and allowance for nonexchangeability across trial parameters. Two applications will be discussed: phase II adaptive design using historical data; and, a phase I combination trial in Oncology, which takes advantage of co-data from completed and ongoing phase I trials.