Short Course of the 2020 Workshop on Biostatistics and Bioinformatics

Title: Learning and Implementing Bayesian Adaptive Designs

Room 1441, 25 Park Place, Georgia State University, Atlanta, GA 30303

1:30pm-5:30pm, May 08 (Friday), 2020

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Abstract:

Clinical trial is a prescribed learning process for identifying safe and effective treatments. In recent years, rapid advancements in cancer biology, immunology, genomics, and novel treatments demand innovative methods to better identify effective therapies for the most appropriate population in a timely, efficient, accurate, and cost-effective way. In this short course, I will first illustrate the concept of Bayesian update and Bayesian inference, a superior alternative to the traditional frequentist approach. Bayesian methods take the “learn as we go” approach and are innately suitable for clinical trials. Then, I will give an overview of Bayesian adaptive designs in the areas of adaptive dose finding, posterior probability and predictive probability calculation, outcome adaptive randomization, multi-endpoint phase II design, multi-arm platform design, and hierarchical modeling, etc. Particular attention will be devoted on the model assisted designs including the BOIN design and the BOP2 design for Phase I and Phase II trials, respectively. Shiny applications for the design and conduct of clinical trials will be introduced. (http://trialdesign.org).

Bayesian adaptive clinical trial designs increase the study efficiency, allow more flexible trial conduct, and treat more patients with more effective treatments in the trial but also possess desirable frequentist properties. Perspectives will be given on the recent development in clinical trial designs such as master protocols with umbrella and basket studies to enhance success and speed up the drug approval process.
Dr. Lee’s areas of research interest include design and analysis of clinical trials, survival analysis, longitudinal data analysis, statistical computation/graphics, statistical methods for determining drug interaction in combination studies, and cancer chemoprevention. Dr. Lee has been working on the development and application of innovative Bayesian methods for cancer clinical trials, particularly in incorporating multiple biomarkers and adaptive designs for more efficient and ethical clinical trials. Dr. Lee is a Statistical Editor for the *Journal of the National Cancer Institute* and *Cancer Prevention Research*. He is a Fellow of the American Statistical Association, Society for Clinical Trials, and American Association for the Advancement of Science.