Yale SCHOOL OF PUBLIC HEALTH
Biostatistics

A Sequential Basket Trial Design Based on Multi-Source Exchangeability with Predictive Probability Monitoring

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ABSTRACT
Precision medicine endeavors to conform therapeutic interventions to the individuals being treated and needs to account for the heterogeneity of treatment benefit among patients and patient subpopulations. In oncology, basket trials have emerged as an increasingly popular trial design to better address the goals of precision medicine that endeavors to test the effectiveness of a therapeutic strategy among patients defined by the presence of a particular biomarker target rather than a particular cancer type, where the evaluation of treatment effectiveness are conducted with respect to the "baskets" which collectively represent a partition of the targeted patient population. However, many basket trials may be incorporating inefficient statistical methodology with respect to approaches for interim monitoring and sharing information across baskets where they may be potentially exchangeable. In this presentation, we will present novel methodology for a sequential basket trial design with Bayesian interim analyses with predictive probability monitoring and the incorporation of a novel hierarchical modeling strategy for sharing information among a collection of discrete, potentially non-exchangeable subtypes that we contrast with the popular, but inefficient, Simon two-stage design.