

Adaptive Randomization for Personalized Medicine in Cancer Clinical Trials

J. Jack Lee

University of Texas M. D. Anderson Cancer Center, Houston, Texas, USA

Xian Zhou

*University of Texas M. D. Anderson Cancer Center, Houston, Texas, USA and
Genetech Inc., South San Francisco, California, USA*

Suyu Liu

University of Texas M. D. Anderson Cancer Center, Houston, Texas, USA

To study the predictive effect of biomarkers and the efficacy of multiple treatments, we implement an outcome-based adaptive randomization design. The goals are not only to find out whether treatments works and identify their efficacy in different types of patients, but also to best align the most effective treatments to individual patients. The study consists of 4 parallel phase II studies each with a different targeted therapy for lung cancer. A hierarchical Bayes model is used to characterize efficacy rates by treatment and biomarker profile. Based on the posterior clinical efficacy, patients are adaptively randomized according to their biomarker status. The operating characteristics based on simulations indicate that the design can accurately identify the effective biomarker-treatment combinations, and allocates more patients to more efficacious treatments - a step toward "personalizing medicine". Simulation results and practical considerations will be given.

[J. Jack Lee, 1515 Holcombe Blvd. Unit #447, Houston, Texas 77030, U.S.A.; jjlee@mdanderson.org]