

**TITLE: A Bayesian Adaptive Marker-Stratified Design for Phase II Clinical Trials Using Calibrated Spike-and-Slab priors**

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**Abstract:**

The marker-stratified design (MSD) stands as a potent tool for assessing subgroup-specific treatment effects of molecularly targeted agents (MTA). In MSD, patients are classified into the marker-positive and marker-negative subgroups, then randomized for MTA or control treatment within each subgroup. The clinical features of the biomarker and treatments used in MSD offer valuable information for treatment evaluation. Specifically, response rates for patients on the control treatment remain similar across different subgroups if the biomarker involved is not prognostic. Additionally, when the MTA is effective, the marker-positive patients generally exhibit significantly higher response rates compared to the marker-negative patients receiving the same MTA. This paper proposes a Bayesian adaptive design, termed the SSS design, leveraging these clinical features to enhance the efficiency of MSD. The SSS design employs spike-and-slab priors to dynamically share information on response rates across different subgroups. The strength of this information sharing is automatically governed by two posterior probabilities, measuring similarities in response rates between different subgroups. Simulation studies confirm that the proposed SSS design demonstrates favorable operational characteristics.

**Bio:**

Dr. Yong Zang is the Indiana University School of Medicine Showalter Scholar Associate Professor. He also serves as the Co-Director of Clinical Research for the Biostatistics and Data Management Core, IU Simon Comprehensive Cancer Center. He received his Ph.D. degree from The University of Hong Kong and finished his Postdoctoral training in The University of Texas, MD Anderson Cancer Center. His research interests are clinical trial design and statistical genetics. He has published over seventy papers in peer-reviewed statistical, genetics and medical journals such as *Biometrics*, *Biostatistics*, *JRSSC*, *American Journal of Human Genetics*, *Genome Research*, *Cancer Research* and *Clinical Cancer Research*. His research is supported by National Institute of Health, Showalter Trust and Indiana CTSI.