# BAYESIAN ADAPTIVE DESIGNS FOR PHASE III CLINICAL TRIALS

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Abstract:

There is an increasing interest in Bayesian group sequential designs and adaptive randomization designs because of its potential to improve efficiency in clinical trials, to shorten drug development time, and to enhance statistical inference precision without undermining the clinical trial's integrity or validity. We propose two Bayesian adaptive designs, a Bayesian sequential design with adaptive randomization (BSDAR) for continuous outcomes and a Bayesian sequential design for time-to-event outcomes (BSD4TEO). For both designs, alpha spending functions are used to control the overall study-wide type I error rate. In BSDAR, the randomization rate is adaptively changed to attribute newly recruited patients to different treatment arms more efficiently. For BSD4TEO, Bayes factor is adapted for decision-making at interim analyses.

Algorithms are presented to calculate the optimal randomization rate, to make decision rules and to calculate power of the proposed tests for BSDAR. Sensitivity analysis is implemented to evaluate the impact of different choices of prior parameters on choosing critical values. The power of test and the actual sample size of BSDAR are studied through simulations and compared with the traditional Bayesian sequential design or frequentist group sequential design. Simulations show that, when total sample size is fixed, BSDAR can obtain greater power and/or cost smaller actual sample size than the traditional Bayesian sequential design. The feasibility of the BSDAR is further illustrated on a real data set.