

Optimal Group Sequential Designs and Related (In Clinical Trials)

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Adaptive Designs (in Clinical Trials)

I have implemented many adaptive design methods using R or SAS, compared them via simulations, have a manuscript under journal review process on a new combination test for designing a two-stage adaptive design. Additionally, I am interested in topics in this area as follows: 1) comments on regulatory guidance documents on adaptive designs; 2) considerations and optimization of adaptive trial design in clinical development; 3) optimal cost-effective go-no go decisions in clinical development; 4) timing and frequency of interim analyses; 5) approaches for optimal dose selection for adaptive designs; 6) randomization challenges in adaptive design studies; 7) implementing issues; 8) approaches for patient recruitment modeling and simulation.

Survival Analysis

I've done a couple of papers on issues in clinical trial with survival endpoints: 1) sensitivity analyses for informative censoring in survival data; 2) sample size increase during a survival trial when interim results are promising; 3) prediction of the timing of events in clinical trials with survival endpoints; 4) planning a comparative group sequential clinical trial with loss to follow-up and a period of continued observation; 5) planning the duration of a survival group sequential trial with a fixed follow-up time for all subjects.

Statistical Methods in Trials with Sequential Parallel Design for Trials with High Placebo Response

I've done a few researches in this area as follows: 1) optimal weighted Z test and linear combination test in extended sequential parallel designs; 2) covariance and variance evaluations of two estimators for drug-placebo difference in a trial with sequential parallel design; 3) misunderstanding of a new approach to drug-placebo difference calculation in short term antidepressant-drug trials; 4) on clinical trials with a high placebo response rate; 5) an unbiased estimator of the two-period treatment effect in doubly randomized delayed-start (DRDS) designs.

Non-Inferiority Designs

I am also interested in the topics on non-inferiority trials as follows: 1) choice of non-inferiority margin for the mean difference; 2) choice of non-inferiority margin for the mean ratio and hazard ratio; 3) non-inferiority hypotheses with binary endpoints; 4) fixed-margin method and synthesis method; 5) switching between superiority and non-inferiority; 6) non-inferiority trials with three treatment groups; 7) regulatory guidance on non-inferiority trials; 8) Intention-to-treat analysis versus per-protocol analysis in non-inferiority trials.