

A New Bayesian Framework for Master Protocols with Type I Error Control

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Abstract: We consider a new Bayesian framework for master protocols in which hypotheses are treated as random quantities under a Bayesian testing setting. Several benefits come with this framework. First, sample size, operating characteristics, and frequentist properties can be assessed via simulation. Second, Bayesian properties such as conditional probabilities of making a wrong decision, or Bayesian type I error rates can be evaluated. Lastly, Bayesian multiplicity control can be applied based on prior calibration. We show the benefits in terms of frequentist property, e.g., sample size saving, and also in terms of Bayesian property, e.g., the use of prior to control probability of making errors. Examples of real-world trials will be provided. The construction of the Bayesian models involve application of parametric and nonparametric priors. The models can accommodate different types of trials, such as phase 1b expansion cohorts, basket and umbrella trials, and any multi-arm trials with or without the same endpoints.