

COLLOQUIUM

Modeling heterogeneity and its effect on the operating characteristics of a Simon Phase II clinical trial

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Abstract

The homogeneity assumption of a phase II single arm binary clinical trial is commonly violated due to lack of fit of population profile estimates or patient accrual causing Simon's 2-stage design parameters to be violated. Using a general framework to model heterogeneity through heterogeneity classes and heterogeneity imbalance, we investigate the effects of heterogeneity on the operating characteristics of the Simon Phase II clinical trial design using the standard practice of averaging a response profile. We show that under heterogeneity, the Simon designs have unacceptable probabilities of being underpowered or oversized, irrespective of the response profile, under the averaging practice. We propose an adaptive modification to the Simon design to improve its performance.

Department
of
Mathematics

Thursday,
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4:00 p.m.
204 Morgan Hall

Refreshments will be
served at 3:45 p.m.



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