

Generalized Likelihood Ratio Statistics and Uncertainty Adjustments in Efficient Adaptive Design of Clinical Trials

Jay Bartroff, Tze Leung Lai

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A new approach to adaptive design of clinical trials is proposed in a general multiparameter exponential family setting, based on generalized likelihood ratio statistics and optimal sequential testing theory. These designs are easy to implement, maintain the prescribed Type I error probability, and are asymptotically efficient. Practical issues involved in clinical trials allowing mid-course adaptation and the large literature on this subject are discussed, and comparisons between the proposed and existing designs are presented in extensive simulation studies of their finite-sample performance, measured in terms of the expected sample size and power functions.

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