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Wong-Shian Huang and Yuan-chin Ivan Chang

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# Using ROC curve for sample size determination and treatment screening in two-stage Phase II clinical trials

Wong-Shian Huang  
Yuan-chin Ivan Chang  
Institute of Statistical Science  
Academia Sinica, Taiwan

## Abstract

In pharmaceutical-related research, we usually use the methods of clinical trials to identify the valuable treatments and compare their efficacy with that of a standard control therapy. Although clinical trials are essential for ensuring the efficacy and post-marketing safety of a drug, to conduct clinical trials are usually costly and time-consuming. Hence, to recruit patients to the little therapeutic effect treatments is inappropriate due to the ethical and cost imperative. There are several two-stage designs in the literature, where for reducing cost and shortening duration of trials, they use the conditional power obtained from interim analysis results to appraise whether we should continue the lower efficacious treatments into next stage. However, there is a lack of discussions about the influential impacts on the conditional power of a trial at the design stage in the literature. In this article, we calculate the optimal conditional power via the receiver operating characteristic (ROC) curve method to assess the impacts on the quality of a two-stage design with multiple treatments. We propose an optimal design with minimum the expected sample size for choosing the best or some promising treatment(s) among several treatments under an optimal conditional power constraint. In this paper, we provide tables of the two-stage design subject to optimal conditional power for various combinations of design parameters and use an example to illustrate our methods.