Efficient Multi-Stage Design Generator for Phase II Clinical Trials Using Swarm Intelligence Optimization Techniques

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Abstract

In Phase II clinical trials, multi-stage designs offer a strategic advantage by enabling interim analyses that allow for the early termination of trials if the treatment is deemed ineffective. However, with the increasing complexity of modern clinical trials, efficiently generating designs with more stages is challenging. Traditional exhaustive search methods are computationally expensive and lack scalability beyond two or three stages. In this talk, we propose a novel approach utilizing the Particle Swarm Optimization (PSO) algorithm to generate multi-stage designs for Phase II trials. To illustrate the performance of the proposed approach, we consider two commonly used types of designs: the optimal design, which minimizes the expected sample size, and the minimax design, which minimizes the total sample size, both under pre-specified constraints on Type I and Type II errors. Our numerical results demonstrate the effectiveness of PSO in generating both two-stage and three-stage designs. Notably, PSO has discovered some optimal and minimax three-stage designs that outperform those generated by traditional exhaustive search methods. Additionally, for designs involving more than three stages, we discuss PSO parameter configurations that enable the efficient identification of optimal four-stage and five-stage designs.

Keywords: Multi-stage Design, Phase IIA Clinical Trial, Particle Swarm Optimization