“Designs for Clinical Trials: Perspectives on Current Issues”
David Harrington, editor, 2012, 204 pages, Springer, $189

Review by Norman M. Goldfarb

“Designs for Clinical Trials: Perspectives on Current Issues” fills the gap between professional journals and school textbooks by addressing a few important, rapidly evolving statistical topics. The book is intended for statistical practitioners like clinical trialists who actively use statistics but do not follow the literature on recent biostatistical thinking.

As the following excerpt demonstrates, the book provides practical and straightforward explanations:

**Selecting the Criteria for an Adaptive Sample Size Increase**

The operating characteristics of an adaptive design depend in a complicated way on the criteria for increasing the sample size after observing the interim data. These criteria may combine objective information, such as the current estimate of $\delta$ or the current conditional power with assessments of safety, with information available from other clinical trials that was not available at the start of the study. The adaptive approach provides complete flexibility to modify the sample size without having to prespecify a precise mathematical formula for computing the new sample size based on the interim data. However, for confirmatory trials, it is a regulatory requirement that the precise sample-size re-estimation rule be prespecified as far as possible, subject of course to being overruled if there are safety concerns or other matters requiring clinical judgement, at the time of the interim analysis. It is thus instructive to investigate power and expected sample size by simulating the trial under different values of $\delta$ and applying precise prespecified rules for increasing the sample size on the basis of the observed interim results.

The book includes nine chapters:
- Designs for Phase I Trials
- Randomized and Balancing Allocation Schemes for Clinical Trials
- Trials: Computational Perspectives on Design and Deployment
- Sequential Designs for Clinical Trials
- Sample Size Re-estimation for Confirmatory Clinical Trials
- On Stopping a Randomized Clinical Trial for Futility
- Molecular Gene-Signatures and Cancer Clinical Trials
- Targeted Clinical Trials
- Design Issues for Quality of Life Studies Subject to Dropout

The book is available in bookstores.

**Reviewer**
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