

## **"Randomized Clinical Trials: Design, Practice and Reporting"**

**David Machin and Peter M. Fayers, 2010, 361 pages, Wiley-Blackwell, \$70.00**

**Review by Norman M. Goldfarb**

"Randomized Clinical Trials: Design, Practice and Reporting" is a solid introduction for clinical research investigators. The emphasis is on the preparation phase of a study, when many investigators are most actively involved. The 13-page chapter on trial conduct discusses topics such as subject recruiting, data validation, data monitoring committees, protocol modifications, and preparing the publication, but does not say much about good clinical practice and other aspects of day-to-day study conduct. The chapters on statistics are moderately technical. The book makes copious use of examples.

This book has been selected for  
[The First Clinical Research Bookshelf](#)  
Essential reading for clinical research professionals

The text is lucid, as illustrated by this excerpt about interim analyses by data monitoring committees:

The trial design team has to decide on the frequency of such interim analyses and also be aware that multiple looks at (ever accumulating) data on the same endpoint variable raises the same issues as those concerned with multiple endpoints. In this situation, the lack of independence of the successive analyses causes the p-values to become distorted; the greater the number of interim analyses, the greater the distortion. Consider the example of using a continuous endpoint variable for comparing two treatment groups. If the significance level planned for the final analysis of the completed trial is 5%, this level increases to 8%, 14% and 19% if 2, 5 or 10 interim looks, respectively, at the data are made, as shown in Table 8.2. Essentially these imply that the more we look at the data, the more likely are we to reject the null hypothesis even if true. This raises the distinct possibility of inappropriately claiming efficacy and stopping a trial early as a consequence. One way round this difficulty is to introduce a nominal significance level whose value depends on the number of interim analyses planned.

The book consists of 14 chapters:

- Introduction
- Design Features
- The Trial Protocol
- Measurement and Data Capture
- Randomization
- Trial Initiation
- Trial Conduct
- Basics of Analysis
- Trial Size
- Reporting
- Adaptations of the Basic Design
- Paired Designs
- More than Two Interventions

- Further Topics

The book is available in bookstores.

### **Reviewer**

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