

## **"Clinical Trials: A Methodological Perspective, 2<sup>nd</sup> Edition"**

**Steven Piantadosi, 2005, 687 pages, Wiley Interscience, \$125.00**

**Review by Norman M. Goldfarb**

"Clinical Trials: A Methodological Perspective" includes clearly-written, practical presentations of the standard topics, and also fascinating discussions you won't find elsewhere, on subjects such as surgical, prevention, and complementary and alternative medicine trials. It is clear from the book that the author knows way more about clinical research than is probably healthy. The reader's health is similarly threatened.

The book includes 22 chapters:

- Preliminaries
- Clinical Trials as Research
- Why Clinical Trials Are Ethical
- Contexts for Clinical Trials
- Statistical Perspectives
- Clinical Trials as Experimental Design
- Random Error and Bias
- Objectives and Outcomes
- Translational Clinical Trials
- Dose-Finding Designs
- Sample Size and Power
- The Study Cohort
- Treatment Allocation
- Treatment Effects Monitoring
- Counting Subjects and Events
- Estimating Clinical Effects
- Prognostic Factor Analysis
- Reporting and Authorship
- Factorial Designs
- Crossover Designs
- Meta-Analyses
- Misconduct and Fraud in Clinical Research

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

Even complicated statistical material is understandable, for example:

To balance several clinically important prognostic factors, the randomization can be blocked and stratified. Every relevant prognostic factor combination can define an individual stratum, with blocking in each. Then the treatment assignments will be balanced in each stratum, yielding balanced prognostic factors in each treatment group. To be most advantageous, stratification should be used only for prognostic factors with relatively strong effects, such as risk ratios over about 2.0.

The book is available at bookstores.

**Reviewer**

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