

"Clinical Trials: A Practical Guide to Design, Analysis, and Reporting"

Duolao Wang and Ameet Bakhai, editors, 2006, 496 pages, Remedica, \$49.95

Review by Norman M. Goldfarb

"Clinical Trials: A Practical Guide to Design, Analysis, and Reporting" is a very clear exposition of clinical research design, analysis and reporting. It is written at a moderate level of detail, leaving the reader satisfied but not bloated.

The book includes chapters on 38 topics in five sections:

- Fundamentals of Trial Design
- Alternative Trial Designs
- Basics of Statistical Analysis
- Special Trial Issues in Data Analysis
- Reporting of Trials

This book has been selected for
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Essential reading for clinical research professionals

Concise examples enliven the text and clarify complex topics. For example, in a passage on surrogate endpoints, it describes the sad fate of three drugs (encainide, flecainide and moricizine) proven to reduce cardiac arrhythmias. Based on this surrogate measure, the FDA approved these drugs for patients with severely symptomatic arrhythmias. Against all reason, the Cardiac Arrhythmia Suppression trial (CAST) proved that these drugs actually increased mortality.

The section on special trial issues is especially interesting. It discusses, for example, the pros and cons of intent-to-treat vs. per-protocol analysis, and how to adjust for missing data. It points out that the chance of a false positive result increases from 5% with one hypothesis to 40% with ten subgroup hypotheses. For example, the Second International Study of Infarct Survival trial (ISIS-2) proved that aspirin after a heart attack reduces the chance of further heart attacks – except for patients with Gemini and Libra astrological signs.

The book is available in bookstores.

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