

"A Manager's Guide to the Design and Conduct of Clinical Trials, 2nd Edition"

Phillip I. Good, 2006, 256 pages, Wiley-Liss, \$84.95

Review by Norman M. Goldfarb

"A Manager's Guide to the Design and Conduct of Clinical Trials, 2nd Edition" is a pragmatic cookbook for clinical research. With this book in hand, people who manage the people who manage clinical trials can intelligently supervise their staffs. Reading between the lines, it is apparent that the author, in his decades of consulting, has seen many trials that would have benefitted from the book's practical advice.

The book includes 16 chapters, divided into four sections: introduction, plan, do and check:

- Cut Costs and Increase Profits
- Guidelines
- Prescription for Success
- Staffing for Success
- Design Decisions
- Trial Design
- Exception Handling
- Documentation
- Recruiting and Retaining Patients and Physicians
- Computer-Assisted Data Entry
- Data Management
- Are You Ready?
- Monitoring the Trials
- Managing the Trials
- Data Analysis
- Check

Although the book does not provide comprehensive detail, it includes many insights. For example, patients at public hospitals are likely to have multiple unresolved health issues that make them less-than-ideal clinical trial subjects. Academic investigators may lose interest in trials that stretch over several years, especially if they will not generate a publication. A subject manual with simple instructions can improve compliance.

Some of the recommendations will not suit every study. For example, the book recommends active controls because a successful trial will yield good marketing data. Sponsor-paid study coordinators raise cost and conflict-of-interest questions. The author "sees no value" in kick-off investigator meetings and prefers to use the funds for morale-building meetings later in the study. On the other hand, it is refreshing to hear from an author with strong views on controversial topics.

The book is available in bookstores.

Reviewer

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Managing clinical trials, of whatever size and complexity, requires efficient trial management. Trials fail because tried and tested systems handed down through apprenticeships have not been documented, evaluated or published to guide new trialists starting out in this important field. For the past three decades, trialists have invented and reinvented the trial management wheel. However, a good trial manager involved in the trial design and funding application will make a valuable contribution to the practicalities of conducting the trial, potentially saving money and avoiding unworkable systems. Generic job descriptions produced by the HTA [7] and the UK Trial Managers' Network (UKTMN) [8] identify the key responsibilities of a trial manager as follows

Prior to the initiation of any clinical trial, an investigator must become acquainted with the material requirements, personnel needs, and best practices involved in the conduct of the trial. Commitment to a clinical trial should not be taken lightly because even a simple study may require a major investment of staff, space, and time. Standard operating procedures help to standardize staff training and improve regulatory compliance. Reasons for participation in clinical research may differ between community and academic gastroenterologists, but responsibility for patient care, regulatory requirements, and clinical trial design are common to both. Clinical Trials, Second Edition, offers those engaged in clinical trial design a valuable and practical guide. This book takes an integrated approach to incorporate biomedical science, laboratory data of human study, endpoint specification, legal and regulatory aspects and much more with the fundamentals of clinical trial design. It provides an overview of the design options along with the specific details of trial design and offers guidance on how to make appropriate choices. Full of numerous examples and now containing actual decisions from FDA reviewers to better inform trial design, the 2nd Edition... Executive and managerial professionals involved in the design and analysis of clinical experiments, along with clinical research associates, biostatisticians, and students in public health will find A Manager's Guide an indispensable resource. Praise for the First Edition: ". . . readable, informative and at times witty . . . never stops being concise and well written . . . a book worth a read . . ." —Statistics in Medicine. The first practical guide to computer-assisted clinical trials written without use of technical jargon, A Manager's Guide to the Design and Conduct of Clinical Trials provides a comprehensive primer for prospective managers covering every critical issue, including study design, organization, management, and analysis, as well as recruitment, reporting, software, and monitoring. Clinical Trials, Second Edition, offers those engaged in clinical trial design a valuable and practical guide. This book takes an integrated approach to incorporate biomedical science, laboratory data of human study, endpoint specification, legal and regulatory aspects and much more with the fundamentals of clinical trial design. It provides an overview of the design options along with the specific details of trial design and offers guidance on how to make appropriate choices. Full of numerous examples and now containing actual decisions from FDA reviewers to better inform trial design, the 2nd Edition...