Preamble
This book was the 46th in a series of statistics textbooks and monographs edited by DB Owen (Department of Statistics, Southern Methodist University, Dallas, Texas, USA) and RG Cornell (School of Public Health, University of Michigan, Ann Arbor, Michigan, USA, for the publisher Marcel Dekker.

Aims
Advances in clinical research methodology during the past few decades have been extensive in both scope and volume, contributions have appeared in the medical, statistical, epidemiological, social science, and other related literatures, and continue to do so. As a result, becoming well informed can at times seem a Herculean (or even Sisyphean) task. It is thus reasonable to ask why we are adding to this already voluminous literature. Simply put, we feel that this book, rather than compounding the problem, contributes to its solution. Despite increasing efforts to improve communications, the pathways between disciplines can often appear tortuous and discouraging. Although some of the difficulty is substantive, much is attributable to the use of discipline-specific jargon or shorthand. Accordingly, in planning this work we sought a level of presentation that would be useful both to clinicians with varying degrees of methodological expertise (from medical students to seasoned investigators) and to methodologists with differing levels of clinical experience (from theoretical statisticians with an interest in medical applications to applied biostatisticians). This volume is designed to encourage critical thinking about the design and execution of a randomised clinical trial, the strategy generally regarded as the most powerful for the evaluation of medical interventions. By providing a careful examination of fundamental design, conduct, analysis, and reporting issues, this book should improve communication between producers and consumers of clinical trial results, advance both the conduct and understanding of these ethically and scientifically challenging endeavors, and ultimately help promote the development and utilization of effective therapeutic interventions (Preface, pages v and vi).

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Preface (Stanley H Shapiro, Thomas A Louis)
Contributors
Introduction (JC Bailar III)
1. Controversies in design and analysis of clinical trials (F Mosteller, JP Gilbert, B McPeek)
   - The nature of biomedical trials
   - How controversy arises
   - How frequently do innovations succeed?
   - Designs
   - Sample sizes
   - Further special designs
   - Placebo
   - Problems arising from multiple comparisons and selection effects
   - Scoring clinical trials
   - Issues and needs
Do trials cost too much?
Concluding remarks
References

2. On some prerequisites for a successful clinical trial (DL Sackett)
   - The first prerequisite: the trial needs to be
   - The second prerequisite: the trial question is both appropriate and unambiguous
   - The third prerequisite: the trial architecture is valid
   - The fourth prerequisite: the inclusion/exclusion criteria strike a balance between
     efficiency and generalizability
   - The fifth prerequisite: the trial protocol is feasible
   - The sixth prerequisite: the trial administration is effective

References

3. Ethical aspects of clinical trials (K Lebacqz)
   - The role of the IRB
   - Basic ethical principles
   - Informed consent
   - Special populations
   - Privacy and confidentiality
   - Selection of subjects
   - Compensation for injury
   - Risk-benefit calculus
   - Choice of controls
   - Summary and conclusions

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4. Exclusions, losses to follow-up, and withdrawals in clinical trials (P Armitage)
   - Criteria for eligibility
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   - Protocol deviations
   - Conclusion

References

5. The control of bias in clinical trials (TC Chalmers)
   - Bias in clinical trials
   - Identification of authors and sources of support
   - Description of patients accepted and rejected
   - The process of randomisation
   - Blinding of the patient
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6. Practical considerations in the coordination of clinical trials (PT Lavin)
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7. Statistical analysis of clinical trials (P Meier)
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Complex analyses
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8. Reporting the results of a clinical trial (ER Greenberg, T Colton, JA Baron)
   General concerns
   Data presentation
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   Specific content
   Knowing when to stop
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