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"Can You Handle the Truth?"

## "Principles and Practice of Clinical Trial Medicine"

Richard Chin and Bruce Y. Lee, 2008, 547 pages, Elsevier, \$83.95

Review by Norman M. Goldfarb

"Principles and Practice of Clinical Trial Medicine" combines the clear, nontechnical writing of an introductory primer with the somewhat deeper coverage of a handbook and the in-depth discussion, in selected areas, of an advanced text, for example:

- Healthcare providers could introduce sampling biases by referring patients who are difficult, emotionally needy, noncompliant, treatment failures, or disadvantaged (e.g., socioeconomically).
- There are 14 common reasons why study subjects drop out (other opportunity, job conflict, personal issue, psychological issue, relocation, dislike of study personnel, treatment side effect, lack of treatment effect, disease improvement, study requirement, rumor, loss of motivation, peer pressure, and financial constraint) and seven common reasons why it may be necessary to discontinue a study subject (noncompliance, disruptive behavior, broken blind, clinical deterioration, safety concern, selection criteria violation, and ethical or legal conflict/concern).
- Live interviews with subjects have advantages (provide guidance for respondent, cues from respondent, additional probing, increased response rate, and confirm the identity of the respondent) and disadvantages (costly and time-consuming, variability in questions, interviewer interpretation, intrusiveness, and time pressure).
- Nine common reasons for missing data include: instrument failure, noncompliance, failure to record data, value out of measurement range, measurement cannot be made, ethical or legal barrier, error in storing or transferring data, treatment discontinuation, and lost to follow-up.

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

The book consists of 17 chapters:

- Introduction
- Overview of Clinical Research Medicine
- Ethical, Legal, and Regulatory Issues
- Introduction to Clinical Trial Statistics
- Measures and Variables
- Study Groups
- Periods, Sequences, and Trial Design
- Endpoints
- Economics and Patient-Reported Outcomes
- Patient Selection and Sampling
- Dosing and Intervention
- Epidemiology, Decision Analysis, and Simulation
- Study Execution

- Site Selection and Patient Recruitment
- Assessing Data Quality and Transforming Data
- Analysis of Data
- Data Interpretation and Conclusions

The book is available in bookstores.

### **Reviewer**

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