Clinical Trial Biostatistics and Biopharmaceutical Applications

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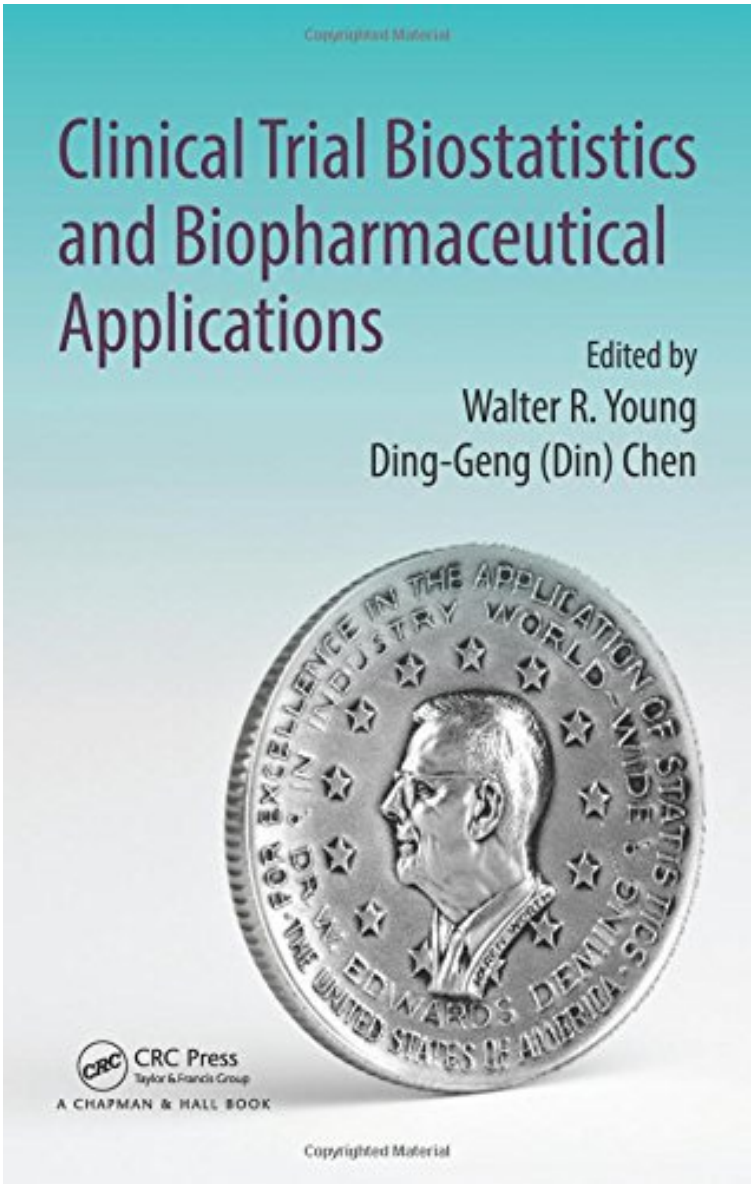

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From Chapman and Hall/CRC : Clinical Trial Biostatistics and Biopharmaceutical Applications before purchasing it in order to gage whether or not it would be worth my time, and all praised Clinical Trial Biostatistics and Biopharmaceutical Applications:

Since 1945, "The Annual Deming Conference on Applied Statistics" has been an important event in the statistics profession. In Clinical Trial Biostatistics and Biopharmaceutical Applications, prominent speakers from past Deming conferences present novel biostatistical methodologies in clinical trials as well as up-to-date biostatistical applications from the pharmaceutical industry. Divided into five sections, the book begins with emerging issues in clinical trial design and analysis, including the roles of modeling and simulation, the pros and cons of randomization procedures, the design of Phase II dose-ranging trials, thorough QT/QTc clinical trials, and assay sensitivity and the constancy assumption in noninferiority trials. The second section examines adaptive designs in drug development, discusses the consequences of group-sequential and adaptive designs, and illustrates group sequential design in R. The third section focuses on oncology clinical trials, covering competing risks, escalation with overdose control (EWOC) dose finding, and interval-censored time-to-event data. In the fourth section, the book describes multiple test problems with applications to adaptive designs, graphical approaches to multiple testing, the estimation of simultaneous confidence intervals for multiple comparisons, and weighted parametric multiple testing methods. The final section discusses the statistical analysis of biomarkers from omics technologies, biomarker strategies applicable to clinical development, and the statistical evaluation of surrogate endpoints. This book clarifies important issues when designing and analyzing clinical trials, including several misunderstood and unresolved challenges. It will help readers choose the right method for their biostatistical application. Each chapter is self-contained with references.

"This book of timely, self-contained chapters covers a wide range of current methods and unresolved challenges in clinical trial statistical methods and will prove to be an essential guide for biostatisticians who work in this field."Dirk F. Moore, Journal of Biopharmaceutical Statistics ". . . the contributed chapters in this collection are clearly written, easily digestible, and well-referenced. The book is a useful resource for the clinical trialist interested in obtaining a quick overview of standard practices and current methodological development for a specific biostatistical application, or a worthwhile read for the researcher seeking to familiarize him or herself with a diversity of emerging topics in clinical trials.Megan T. Smith, University of California, Irvine