Clinical Trial Methodology (Chapman Hall/CRC Biostatistics Series)

Karl E. Peace, Ding-Geng (Din) Chen
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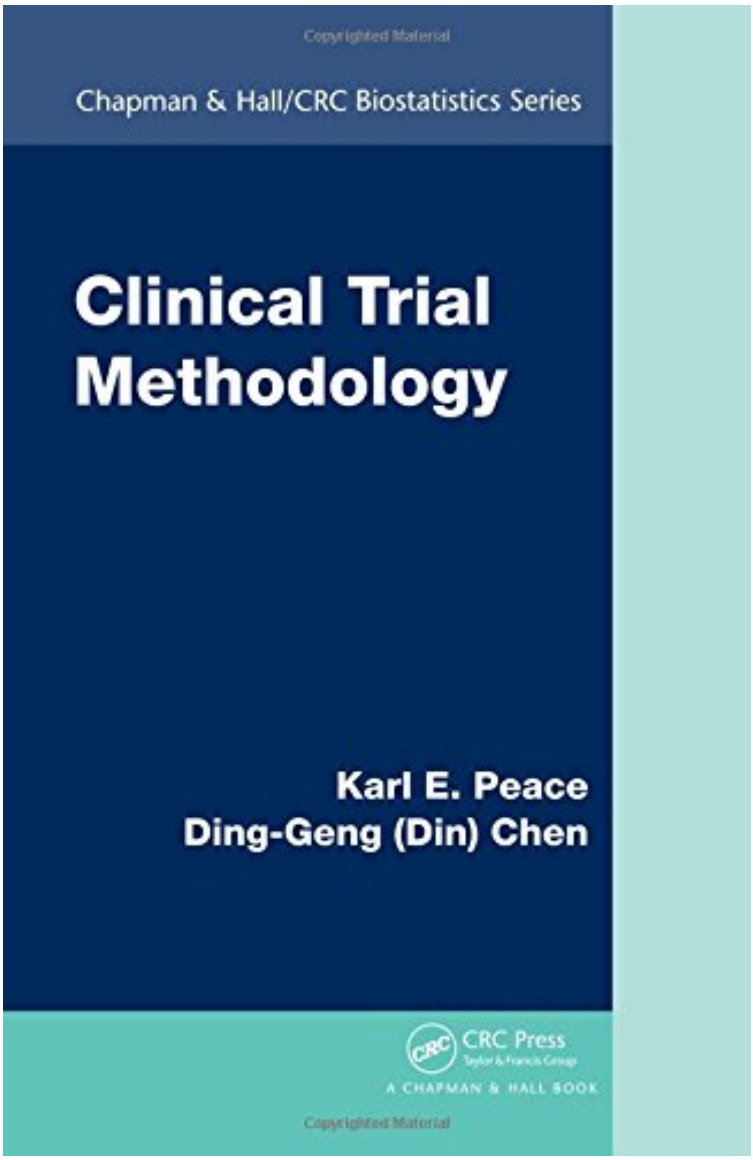

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Karl E. Peace, Ding-Geng (Din) Chen : Clinical Trial Methodology (Chapman Hall/CRC Biostatistics Series) before purchasing it in order to gage whether or not it would be worth my time, and all praised Clinical Trial Methodology (Chapman Hall/CRC Biostatistics Series):

0 of 0 people found the following review helpful. Great BookBy raindrops100Great book. Was my Semester Text

book. Very detailed, from a great teacher.Strongly recommend it. There may be later versions, I wish the data-sets came on Cd's so that its easy to copy that into SAS, or it had a link to a website where u can download the data-sets examples.

Now viewed as its own scientific discipline, clinical trial methodology encompasses the methods required for the protection of participants in a clinical trial and the methods necessary to provide a valid inference about the objective of the trial. Drawing from the authors courses on the subject as well as the first authors more than 30 years working in the pharmaceutical industry, Clinical Trial Methodology emphasizes the importance of statistical thinking in clinical research and presents the methodology as a key component of clinical research. From ethical issues and sample size considerations to adaptive design procedures and statistical analysis, the book first covers the methodology that spans every clinical trial regardless of the area of application. Crucial to the generic drug industry, bioequivalence clinical trials are then discussed. The authors describe a parallel bioequivalence clinical trial of six formulations incorporating group sequential procedures that permit sample size re-estimation. The final chapters incorporate real-world case studies of clinical trials from the authors own experiences. These examples include a landmark Phase III clinical trial involving the treatment of duodenal ulcers and Phase III clinical trials that contributed to the first drug approved for the treatment of Alzheimers disease. Aided by the U.S. FDA, the U.S. National Institutes of Health, the pharmaceutical industry, and academia, the area of clinical trial methodology has evolved over the last six decades into a scientific discipline. This guide explores the processes essential for developing and conducting a quality clinical trial protocol and providing quality data collection, biostatistical analyses, and a clinical study report, all while maintaining the highest standards of ethics and excellence.

This comprehensive text introduces the key areas of clinical trial methodology from the perspective of the biostatistician in the pharmaceutical industry. Throughout, the text benefits from a highly structured and logical flow the arguments made in the book are grounded in many years of practical experience in drug development and at the very least will act as a prompt for in-depth discussion or critical review of ones own perceptions. Clinical Trial Methodology will be of substantial value to early career pharmaceutical industry statisticians.Christopher J. Weir, Pharmaceutical Statistics, 2012 informative discussions of mechanisms such as IND and NDA are unique strengths of this book, distinguishing it from the many other clinical trial texts available. Case studies are presented carefully The authors writing style is disciplined, careful, and informative. this is a helpful and informative book, a nice reference to have for most biostatisticians working on clinical trials.Mithat Gnen, Journal of Biopharmaceutical Statistics, 21, 2011 The book is an excellent overview predicated on the first authors seasoned experiences in designing, analyzing, and communicating the results of clinical trials across a broad number of medical disciplines. A nice introductory feature is the history of drug law and regulation, which helps to frame the subsequent statistical discussion nicely. The real-world examples that dominate the last few chapters are fantastic. There is nothing like a series of examples from an experienced clinical trialist to whet the appetite of those involved in the noble enterprise of medical (and more specifically pharmaceutical) research with the goal of improving the publics health. This book does an admirable job in giving the regulatory and statistical foundations for clinical trials, coupled with real-world examples of how statistical methodology has guided the development of important medicines. Gregory EnasAbout the AuthorKarl E. Peace is the Georgia Cancer Coalition Distinguished Cancer Scholar, founding director of the Center for Biostatistics, and professor of biostatistics in the Jiann-Ping Hsu College of Public Health at Georgia Southern University. Din Chen is the Karl E. Peace Endowed Eminent Scholar Chair in Biostatistics and professor of biostatistics in the Jiann-Ping Hsu College of Public Health at Georgia Southern University.