Design and Analysis of Clinical Trials: Concepts and Methodologies

Shein-Chung Chow, Jen-Pei Liu
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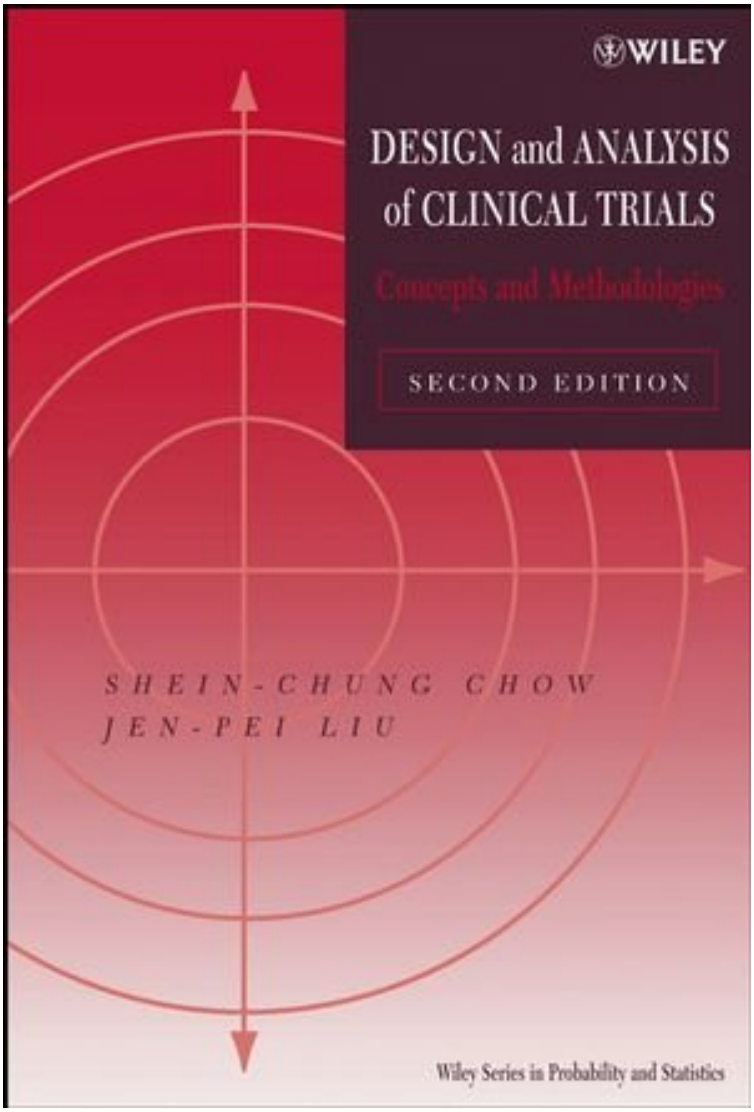

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Shein-Chung Chow, Jen-Pei Liu : Design and Analysis of Clinical Trials: Concepts and Methodologies before purchasing it in order to gage whether or not it would be worth my time, and all praised Design and Analysis of Clinical Trials: Concepts and Methodologies:

4 of 4 people found the following review helpful. DisappointedBy Robert P. HirschI selected this text for a new doctoral level course on clinical trials based mostly on the topics covered. When we started using it, I found many errors in logical thinking. So far, one of the worst is a view that randomization satisfies some statistical assumption. It does not. Its function is to make groups similar, on the average. It is not in any way a substitute for random sampling.

Separating these two random processes is basic to understanding clinical trials. I am embarrassed that I had my students purchase this book.0 of 0 people found the following review helpful. Five StarsBy gerardo i. hurtadothank you!...16 of 16 people found the following review helpful. Most complete reference on the topicBy Brant InmanI own several books on clinical trials and this one is my favorite. It is biblical in its treatment of the topic and always seems to contain what my other books don't.There are a few strengths that are particularly worth pointing out:1) Makes many references to regulatory guidelines.2) Excellent coverage of the various trial designs.3) Good sample size chapter.4) Several chapters on how to practically implement a trial.Other options include:-Piantodosi (Clinical Trials: methodologic perspective): my second favorite, not as comprehensive as Chow and Liu-Freidman and DeMets (Fundamentals of Clinical Trials): a bit too superficial but very well written-Pocock (Clinical trials: practical approach): a bit dated and superficial

Praise for the First Edition of Design and Analysis of Clinical Trials "An excellent book, providing a discussion of the clinical trial process from designing the study through analyzing the data, and to regulatory requirement . . . could easily be used as a classroom text to understand the process in the new drug development area." Statistical Methods in Medicine A complete and balanced presentation now revised, updated, and expanded As the field of research possibilities expands, the need for a working understanding of how to carry out clinical trials only increases. New developments in the theory and practice of clinical research include a growing body of literature on the subject, new technologies and methodologies, and new guidelines from the International Conference on Harmonization (ICH). Design and Analysis of Clinical Trials, Second Edition provides both a comprehensive, unified presentation of principles and methodologies for various clinical trials, and a well-balanced summary of current regulatory requirements. This unique resource bridges the gap between clinical and statistical disciplines, covering both fields in a lucid and accessible manner. Thoroughly updated from its first edition, the Second Edition of Design and Analysis of Clinical Trials features new topics such as: Clinical trials and regulations, especially those of the ICH Clinical significance, reproducibility, and generalizability Goals of clinical trials and target population New study designs and trial types Sample size determination on equivalence and noninferiority trials, as well as comparing variabilities Also, three entirely new chapters cover: Designs for cancer clinical trials Preparation and implementation of a clinical protocol Data management of a clinical trial Written with the practitioner in mind, the presentation assumes only a minimal mathematical and statistical background for its reader. Instead, the writing emphasizes real-life examples and illustrations from clinical case studies, as well as numerous references-280 of them new to the Second Edition-to the literature. Design and Analysis of Clinical Trials, Second Edition will benefit academic, pharmaceutical, medical, and regulatory scientists/researchers, statisticians, and graduate-level students in these areas by serving as a useful, thorough reference source for clinical research.

"It stands ready to satisfy the appetite of any pharmaceutical scientist with a respectable statistical appetite." (Journal of Clinical Research, June 2008) "Biostatisticians, applied statisticians, and clinical scientists will find this book very valuable, and it is suitable for a graduate level clinical trial course." (Journal of Statistical Computation and Simulation, September 2005) "a comprehensive introductionhighly recommended" (Statistical Methods in Medical Research, Vol. 14, 2005) "I will find this book a handy resource for future consulting with medical researchers." (Journal of the American Statistical Association, June 2005) "the authors have done a commendable job of blending large amounts of statistical and regulatory information in a way that is easy to comprehend and directly applicable" (Clinical Chemistry, April 2005) "provides a comprehensive overview of the rather general area of clinical trialsan essential reference text." (Journal of Applied Statistics, Vol.32, No.3, April 2005) "Numerous real-life examples and illustrations form clinical case studies are included" (Zentralblatt Math, Vol.1050, 2005) "certainly comprehensive...should be a standard reference for both clinical scientists and biostatisticians" (Technometrics, February 2005)From the Back CoverPraise for the First Edition of Design and Analysis of Clinical Trials "An excellent book, providing a discussion of the clinical trial process from designing the study through analyzing the data, and to regulatory requirement . . . could easily be used as a classroom text to understand the process in the new drug development area." Statistical Methods in Medicine A complete and balanced presentation now revised, updated, and expanded As the field of research possibilities expands, the need for a working understanding of how to carry out clinical trials only increases. New developments in the theory and practice of clinical research include a growing body of literature on the subject, new technologies and methodologies, and new guidelines from the International Conference on Harmonization (ICH). Design and Analysis of Clinical Trials, Second Edition provides both a comprehensive, unified presentation of principles and methodologies for various clinical trials, and a well-balanced summary of current regulatory requirements. This unique resource bridges the gap between clinical and statistical disciplines, covering both fields in a lucid and accessible manner. Thoroughly updated from its first edition, the Second Edition of Design and Analysis of Clinical Trials features new topics such as: Clinical trials and regulations, especially those of the ICH Clinical significance, reproducibility, and generalizability Goals of clinical trials and target population New study designs and trial types Sample size determination on equivalence and noninferiority trials, as

well as comparing variabilities Also, three entirely new chapters cover: Designs for cancer clinical trials Preparation and implementation of a clinical protocol Data management of a clinical trial Written with the practitioner in mind, the presentation assumes only a minimal mathematical and statistical background for its reader. Instead, the writing emphasizes real-life examples and illustrations from clinical case studies, as well as numerous references280 of them new to the Second Editionto the literature. Design and Analysis of Clinical Trials, Second Edition will benefit academic, pharmaceutical, medical, and regulatory scientists/researchers, statisticians, and graduate-level students in these areas by serving as a useful, thorough reference source for clinical research.About the AuthorSHEIN-CHUNG CHOW, PhD, is currently Vice President of Biostatistics and Clinical Data Management for Millennium Pharmaceuticals, Inc., in Cambridge, Massachusetts. JEN-PEI LIU, PhD, is currently Professor of Statistics for the National Cheng kung University in Tainan, Taiwan, and an investigator for the National Health Research Institutes in Taipei, Taiwan. Both authors have extensive background experience in industry and academia, and, collectively, have published well over a dozen books in their respective fields of study.