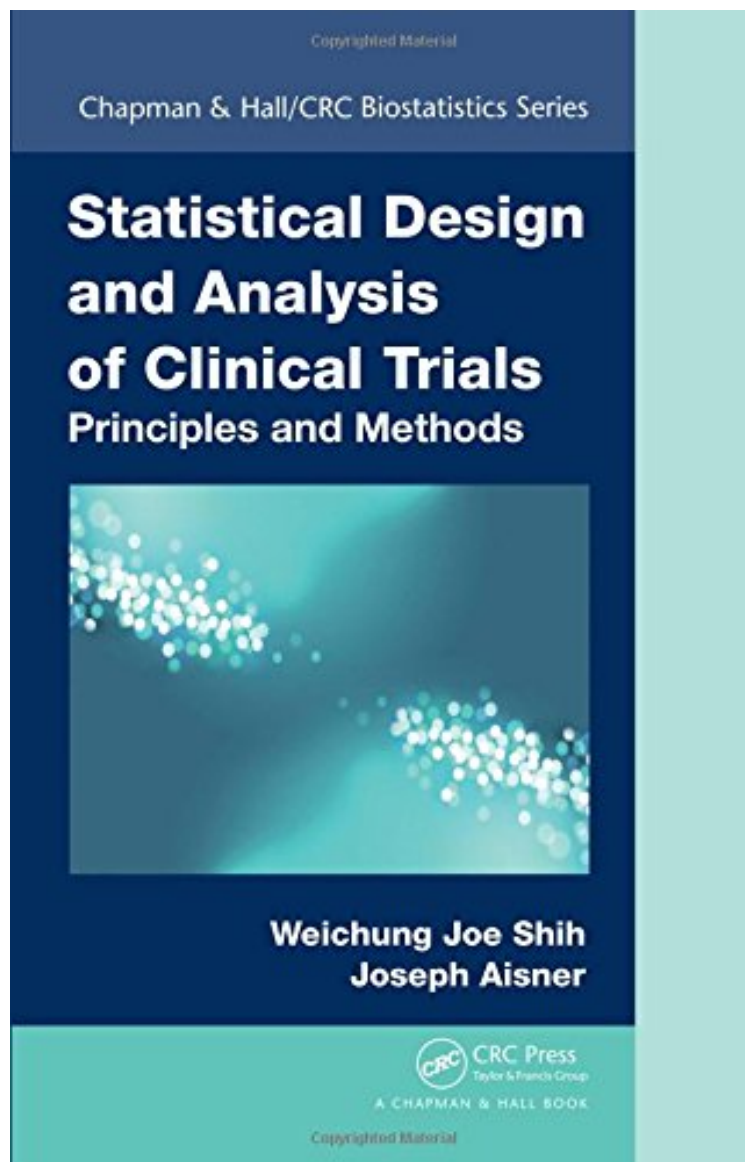


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Statistical Design and Analysis of Clinical Trials: Principles and Methods (Chapman Hall/CRC Biostatistics Series)

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When I studied my MPH degree at Rutgers School of Public Health, I had taken Dr. Shihs course Clinical Trials: Design and Analysis of Medical Experiments using this book. I strongly recommend this book for graduate-level students who wish to start a career in pharmaceutical industry or for those experienced in clinical trials as a reference book. This book opens the gateway for my further ScD studies at Johns Hopkins Bloomberg School of Public Health. There are three major advantages of the book that I would like to highlight. First, it explains profound biostatistic theories into an easy-to-understand approach. This book is worth a read not only for biostatistician, but also for medical students, residents, and public health students and professionals who are interested in developing clinical trials. This book provides essential topics of clinical trial design: Methods of Randomization, Cross-Over Design, Sample Size and Power Calculations, Sequential Design and Methods. These concepts are well discussed, enabling the readers to participate in a clinical trial team and develop of a trial protocol. Second, the book explains complex statistical analyses adequate for understanding and applications. Using the statistical packages to analyze and report real data, readers would be able to communicate clinical trial results both orally and in writing. Some chapters used recent published medical literature (e.g. JAMA, Clinical Cancer Research) to explain how to design the Methods and Statistical Analysis of a clinical trial and how to criticize statistical methodology. Third, this book is one of limited clinical trial books coming with homework at the end of each chapter. These well-written homework make the essential theories more easier to digest and implement in real-life experimental studies. Overall, I highly recommend this book to students, residents, and public health professionals who want to apply basic theory and statistical methods to problems relevant to clinical trials.

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By Joseph Yongsuk Kwon
Statistical Design and Analysis of Clinical Trials: Principles and Methods is the result of many years experience as a leading biostatistician at comprehensive cancer centers. This book singularly demonstrates relevant biostatistical concepts using numerous clinical scenarios. Readers will appreciate his insight and will gain a deeper understanding of the ins and outs of clinical trial designs and methods.

2 of 2 people found the following review helpful. A Book Worth Reading
By Jay Herson Shih and Aisner
have provided a remarkable book on clinical trials. Beginning with "What is a Clinical Trial?" through "Elicitation of the Shape Parameter of the Beta Distribution" this is a book for those new to the art and science of clinical trials as well as experienced practitioners be they biostatisticians or clinicians. The homework at the end of each chapter reviews the fundamentals of the chapter but some challenge even the experienced trialist. These homework problems have, no doubt, stood the test of time from the authors' teaching experience at Rutgers. Both authors have considerable practical experience in clinical trials in both pharma industry and federal grant supported trials and this experience comes out in every page. I enthusiastically recommend this book to people involved or about to become involved in clinical trials.

Statistical Design and Analysis of Clinical Trials: Principles and Methods concentrates on the biostatistics component of clinical trials. Developed from the authors courses taught to public health and medical students, residents, and fellows during the past 15 years, the text shows how biostatistics in clinical trials is an integration of many fundamental scientific principles and statistical methods. Teach Your Students How to Design, Monitor, and Analyze Clinical Trials The book begins with ethical and safety principles, core trial design concepts, the principles and methods of sample size and power calculation, and analysis of covariance and stratified analysis. It then focuses on sequential designs and methods for two-stage Phase II cancer trials to Phase III group sequential trials, covering monitoring safety, futility, and efficacy. The authors also discuss the development of sample size reestimation and adaptive group sequential procedures, explain the concept of different missing data processes, and describe how to analyze incomplete data by proper multiple imputations. Turn Your Students into Better Clinical Trial Investigators This text reflects the academic research, commercial development, and public health aspects of clinical trials. It gives students a multidisciplinary understanding of the concepts and techniques involved in designing and analyzing various types of trials. The books balanced set of homework assignments and in-class exercises are appropriate for students in (bio)statistics, epidemiology, medicine, pharmacy, and public health.

About the Author
Weichung Joe Shih, PhD, is professor and chair of the Department of Biostatistics in the Rutgers School of Public Health at Rutgers University, and director of the Biometrics Division at the Rutgers Cancer Institute of New Jersey. He is an elected fellow of the American Statistical Association and an elected member of the International Statistical Institute. He served on the advisory board of the U.S. FDA for reviewing new drug applications and was associate editor of professional journals, including Statistics in Medicine, Controlled Clinical Trials, Clinical Cancer Research, Statistics in Biopharmaceutical Research, and Statistics in Bioscience. His research interests include adaptive designs and missing data issues. Joseph Aisner, MD, is a professor of medicine and a professor of environmental and occupational medicine at the Robert Wood Johnson Medical School of Rutgers University, director of the Medical Oncology Unit at the Robert Wood Johnson University Hospital, and co-leader of the Clinical Investigations Program at the Rutgers Cancer Institute of New Jersey. He is a fellow of the American College of Physicians and the American Society of Clinical Oncology. He serves on and chairs several National Data

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