

Chapman & Hall/CRC Biostatistics Series

# **Clinical Trial Methodology**

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



**CRC Press**

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A CHAPMAN & HALL BOOK

# Clinical Trial Methodology Chapman Hallcrc Biostatistics Series

**Zhe Xu**



## **Clinical Trial Methodology Chapman Hallcra Biostatistics Series:**

*Bayesian Adaptive Methods for Clinical Trials* Scott M. Berry, Bradley P. Carlin, J. Jack Lee, Peter Muller, 2010-07-19

Already popular in the analysis of medical device trials adaptive Bayesian designs are increasingly being used in drug development for a wide variety of diseases and conditions from Alzheimer's disease and multiple sclerosis to obesity diabetes hepatitis C and HIV Written by leading pioneers of Bayesian clinical trial designs **Bayesian Adaptive Statistical Design, Monitoring, and Analysis of Clinical Trials** Weichung Joe Shih, Joseph Aisner, 2021-10-25 Statistical Design Monitoring and Analysis of Clinical Trials Second Edition concentrates on the biostatistics component of clinical trials This new edition is updated throughout and includes five new chapters Developed from the authors courses taught to public health and medical students residents and fellows during the past 20 years the text shows how biostatistics in clinical trials is an integration of many fundamental scientific principles and statistical methods 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 phase 2/3 seamless design and trials with predictive biomarkers exploit multiple testing procedures and explain the concept of estimand intercurrent events and different missing data processes and describe how to analyze incomplete data by proper multiple imputations This text reflects the academic research commercial development and public health aspects of clinical trials It gives students and practitioners a multidisciplinary understanding of the concepts and techniques involved in designing monitoring and analyzing various types of trials The book's balanced set of homework assignments and in class exercises are appropriate for students and researchers in biostatistics epidemiology medicine pharmacy and public health **Handbook of Methods for Designing, Monitoring, and Analyzing**

**Dose-Finding Trials** John O'Quigley, Alexia Iasonos, Björn Bornkamp, 2017-04-27 Handbook of Methods for Designing Monitoring and Analyzing Dose Finding Trials gives a thorough presentation of state of the art methods for early phase clinical trials The methodology of clinical trials has advanced greatly over the last 20 years and arguably nowhere greater than that of early phase studies The need to accelerate drug development in a rapidly evolving context of targeted therapies immunotherapy combination treatments and complex group structures has provided the stimulus to these advances Typically we deal with very small samples sequential methods that need to be efficient while at the same time adhering to ethical principles due to the involvement of human subjects Statistical inference is difficult since the standard techniques of maximum likelihood do not usually apply as a result of model misspecification and parameter estimates lying on the boundary of the parameter space Bayesian methods play an important part in overcoming these difficulties but nonetheless require special consideration in this particular context The purpose of this handbook is to provide an expanded summary of the field

as it stands and also through discussion provide insights into the thinking of leaders in the field as to the potential developments of the years ahead With this goal in mind we present An introduction to the field for graduate students and novices A basis for more established researchers from which to build A collection of material for an advanced course in early phase clinical trials A comprehensive guide to available methodology for practicing statisticians on the design and analysis of dose finding experiments An extensive guide for the multiple comparison and modeling MCP Mod dose finding approach adaptive two stage designs for dose finding as well as dose time response models and multiple testing in the context of confirmatory dose finding studies John O Quigley is a professor of mathematics and research director at the French National Institute for Health and Medical Research based at the Faculty of Mathematics University Pierre and Marie Curie in Paris France He is author of Proportional Hazards Regression and has published extensively in the field of dose finding Alexia Iasonos is an associate attending biostatistician at the Memorial Sloan Kettering Cancer Center in New York She has over one hundred publications in the leading statistical and clinical journals on the methodology and design of early phase clinical trials Dr Iasonos has wide experience in the actual implementation of model based early phase trials and has given courses in scientific meetings internationally Björn Bornkamp is a statistical methodologist at Novartis in Basel Switzerland researching and implementing dose finding designs in Phase II clinical trials He is one of the co developers of the MCP Mod methodology for dose finding and main author of the DoseFinding R package He has published numerous papers on dose finding nonlinear models and Bayesian statistics and in 2013 won the Royal Statistical Society award for statistical excellence in the pharmaceutical industry

*Statistical Design and Analysis of Clinical Trials* Weichung Joe Shih, Joseph Aisner, 2015-07-28

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 fields

**Inference Principles for Biostatisticians** Ian C. Marschner, 2014-12-11 Designed for students training to become biostatisticians as well as practicing biostatisticians Inference Principles for Biostatisticians presents the theoretical and conceptual foundations of biostatistics It covers the theoretical underpinnings essential to understanding subsequent core methodologies in the field Drawing on his extensive experience

*Adaptive Design Methods in Clinical Trials* Shein-Chung Chow, Mark Chang, 2011-12-01

With new statistical and scientific issues arising in adaptive clinical trial design including the U S FDA's recent draft guidance a new edition of one of the first books on the topic is needed Adaptive Design Methods in Clinical Trials Second Edition reflects recent developments and regulatory positions on the use of adaptive designs in clinical trials

Clinical Trial Data Analysis Using R Ding-Geng (Din) Chen, Karl E. Peace, 2010-12-14 Too often in biostatistical research and clinical trials a knowledge gap exists between developed statistical methods and the applications of these methods Filling this gap Clinical Trial Data Analysis Using R provides a thorough presentation of biostatistical analyses of clinical trial data and shows step by

step how to implement the statistical methods using R The book's practical detailed approach draws on the authors 30 years of real world experience in biostatistical research and clinical development Each chapter presents examples of clinical trials based on the authors actual experiences in clinical drug development Various biostatistical methods for analyzing the data are then identified The authors develop analysis code step by step using appropriate R packages and functions This approach enables readers to gain an understanding of the analysis methods and R implementation so that they can use R to analyze their own clinical trial data With step by step illustrations of R implementations this book shows how to easily use R to simulate and analyze data from a clinical trial It describes numerous up to date statistical methods and offers sound guidance on the processes involved in clinical trials

**Quantitative Methods for HIV/AIDS Research** Cliburn Chan, Michael G. Hudgens, Shein-Chung Chow, 2017-08-07 Quantitative Methods in HIV AIDS Research provides a comprehensive discussion of modern statistical approaches for the analysis of HIV AIDS data The first section focuses on statistical issues in clinical trials and epidemiology that are unique to or particularly challenging in HIV AIDS research the second section focuses on the analysis of laboratory data used for immune monitoring biomarker discovery and vaccine development the final section focuses on statistical issues in the mathematical modeling of HIV AIDS pathogenesis treatment and epidemiology This book brings together a broad perspective of new quantitative methods in HIV AIDS research contributed by statisticians and mathematicians immersed in HIV research many of whom are current or previous leaders of CFAR quantitative cores It is the editors hope that the work will inspire more statisticians mathematicians and computer scientists to collaborate and contribute to the interdisciplinary challenges of understanding and addressing the AIDS pandemic

Benefit-Risk Assessment Methods in Medical Product Development Qi Jiang, Weili He, 2017-12-19 Guides You on the Development and Implementation of B R Evaluations Benefit Risk Assessment Methods in Medical Product Development Bridging Qualitative and Quantitative Assessments provides general guidance and case studies to aid practitioners in selecting specific benefit risk B R frameworks and quantitative methods Leading experts from industry regulatory agencies and academia present practical examples lessons learned and best practices that illustrate how to conduct structured B R assessment in clinical development and regulatory submission The first section of the book discusses the role of B R assessments in medicine development and regulation the need for both a common B R framework and patient input into B R decisions and future directions The second section focuses on legislative and regulatory policy initiatives as well as decisions made at the U S FDA's Center for Devices and Radiological Health The third section examines key elements of B R evaluations in a product's life cycle such as uncertainty evaluation and quantification quantifying patient B R trade off preferences ways to identify subgroups with the best B R profiles and data sources used to assist B R assessment The fourth section equips practitioners with tools to conduct B R evaluations including assessment methodologies a quantitative joint modeling and joint evaluation framework and several visualization tools The final section presents a rich collection of case studies With top specialists

sharing their in depth knowledge thought provoking considerations and practical advice this book offers comprehensive coverage of B R evaluation methods tools and case studies It gives practitioners a much needed toolkit to develop and conduct their own B R evaluations

*Interval-Censored Time-to-Event Data* Ding-Geng (Din) Chen, Jianguo Sun, Karl E. Peace, 2012-07-19 Interval Censored Time to Event Data Methods and Applications collects the most recent techniques models and computational tools for interval censored time to event data Top biostatisticians from academia

biopharmaceutical industries and government agencies discuss how these advances are impacting clinical trials and biomedical research Divid **Design of Experiments and Advanced Statistical Techniques in Clinical Research**

Basavarajaiah D. M., Bhamidipati Narasimha Murthy, 2020-11-05 Recent Statistical techniques are one of the basal evidence for clinical research a pivotal in handling new clinical research and in evaluating and applying prior research This book explores various choices of statistical tools and mechanisms analyses of the associations among different clinical attributes It uses advanced statistical methods to describe real clinical data sets when the clinical processes being examined are still in the process This book also discusses distinct methods for building predictive and probability distribution models in clinical situations and ways to assess the stability of these models and other quantitative conclusions drawn by realistic experimental data sets Design of experiments and recent posthoc tests have been used in comparing treatment effects and precision of the experimentation This book also facilitates clinicians towards understanding statistics and enabling them to follow and evaluate the real empirical studies formulation of randomized control trial that pledge insight evidence base for clinical practices This book will be a useful resource for clinicians postgraduates scholars in medicines clinical research beginners and academicians to nurture high level statistical tools with extensive scope [Encyclopedia of Biopharmaceutical Statistics](#)

[- Four Volume Set](#) Shein-Chung Chow, 2018-09-03 Since the publication of the first edition in 2000 there has been an explosive growth of literature in biopharmaceutical research and development of new medicines This encyclopedia 1 provides a comprehensive and unified presentation of designs and analyses used at different stages of the drug development process 2 gives a well balanced summary of current regulatory requirements and 3 describes recently developed statistical methods in the pharmaceutical sciences Features of the Fourth Edition 1 78 new and revised entries have been added for a total of 308 chapters and a fourth volume has been added to encompass the increased number of chapters 2 Revised and updated entries reflect changes and recent developments in regulatory requirements for the drug review approval process and statistical designs and methodologies 3 Additional topics include multiple stage adaptive trial design in clinical research translational medicine design and analysis of biosimilar drug development big data analytics and real world evidence for clinical research and development 4 A table of contents organized by stages of biopharmaceutical development provides easy access to relevant topics About the Editor Shein Chung Chow Ph D is currently an Associate Director Office of Biostatistics U S Food and Drug Administration FDA Dr Chow is an Adjunct Professor at Duke University School of Medicine as well as Adjunct

Professor at Duke NUS Singapore and North Carolina State University Dr Chow is the Editor in Chief of the Journal of Biopharmaceutical Statistics and the Chapman Hall CRC Biostatistics Book Series and the author of 28 books and over 300 methodology papers He was elected Fellow of the American Statistical Association in 1995

Design and Analysis of Pragmatic Trials Song Zhang, Chul Ahn, Hong Zhu, 2023-05-16 This book begins with an introduction of pragmatic cluster randomized trials PCTs and reviews various pragmatic issues that need to be addressed by statisticians at the design stage It discusses the advantages and disadvantages of each type of PCT and provides sample size formulas sensitivity analyses and examples for sample size calculation The generalized estimating equation GEE method will be employed to derive sample size formulas for various types of outcomes from the exponential family including continuous binary and count variables Experimental designs that have been frequently employed in PCTs will be discussed including cluster randomized designs matched pair cluster randomized design stratified cluster randomized design stepped wedge cluster randomized design longitudinal cluster randomized design and crossover cluster randomized design It demonstrates that the GEE approach is flexible to accommodate pragmatic issues such as hierarchical correlation structures different missing data patterns randomly varying cluster sizes etc It has been reported that the GEE approach leads to under estimated variance with limited numbers of clusters The remedy for this limitation is investigated for the design of PCTs This book can assist practitioners in the design of PCTs by providing a description of the advantages and disadvantages of various PCTs and sample size formulas that address various pragmatic issues facilitating the proper implementation of PCTs to improve health care It can also serve as a textbook for biostatistics students at the graduate level to enhance their knowledge or skill in clinical trial design

**Key Features** Discuss the advantages and disadvantages of each type of PCTs and provide sample size formulas sensitivity analyses and examples Address an unmet need for guidance books on sample size calculations for PCTs A wide variety of experimental designs adopted by PCTs are covered The sample size solutions can be readily implemented due to the accommodation of common pragmatic issues encountered in real world practice Useful to both academic and industrial biostatisticians involved in clinical trial design Can be used as a textbook for graduate students majoring in statistics and biostatistics

Empirical Likelihood Method in Survival Analysis Mai Zhou, 2015-06-17 Empirical Likelihood Method in Survival Analysis explains how to use the empirical likelihood method for right censored survival data The author uses R for calculating empirical likelihood and includes many worked out examples with the associated R code The datasets and code are available for download on his website and CRAN The book focuses on all the standard survival analysis topics treated with empirical likelihood including hazard functions cumulative distribution functions analysis of the Cox model and computation of empirical likelihood for censored data It also covers semi parametric accelerated failure time models the optimality of confidence regions derived from empirical likelihood or plug in empirical likelihood ratio tests and several empirical likelihood confidence band results While survival analysis is a classic area of statistical study the empirical

likelihood methodology has only recently been developed Until now just one book was available on empirical likelihood and most statistical software did not include empirical likelihood procedures Addressing this shortfall this book provides the functions to calculate the empirical likelihood ratio in survival analysis as well as functions related to the empirical likelihood analysis of the Cox regression model and other hazard regression models **Bayesian Analysis Made Simple** Phil

Woodward,2016-04-19 Although the popularity of the Bayesian approach to statistics has been growing for years many still think of it as somewhat esoteric not focused on practical issues or generally too difficult to understand Bayesian Analysis Made Simple is aimed at those who wish to apply Bayesian methods but either are not experts or do not have the time to cre

*Medical Product Safety Evaluation* Jie Chen,Joseph Heyse,Tze Leung Lai,2018-09-03 Medical Product Safety Evaluation Biological Models and Statistical Methods presents cutting edge biological models and statistical methods that are tailored to specific objectives and data types for safety analysis and benefit risk assessment Some frequently encountered issues and challenges in the design and analysis of safety studies are discussed with illustrative applications and examples Medical Product Safety Evaluation Biological Models and Statistical Methods presents cutting edge biological models and statistical methods that are tailored to specific objectives and data types for safety analysis and benefit risk assessment Some frequently encountered issues and challenges in the design and analysis of safety studies are discussed with illustrative applications and examples The book is designed not only for biopharmaceutical professionals such as statisticians safety specialists pharmacovigilance experts and pharmacoepidemiologists who can use the book as self learning materials or in short courses or training programs but also for graduate students in statistics and biomedical data science for a one semester course Each chapter provides supplements and problems as more readings and exercises **Oncology Clinical Trials**

William Kevin Kelly,Susan Halabi,2018-03-28 The second edition of Oncology Clinical Trials has been thoroughly revised and updated and now contains the latest designs and methods of conducting and analyzing cancer clinical trials in the era of precision medicine with biologic agents including trials investigating the safety and efficacy of targeted therapies immunotherapies and combination therapies as well as novel radiation therapy modalities Now divided into six sections this revamped book provides the necessary background and expert guidance from the principles governing oncology clinical trials to the innovative statistical design methods permeating the field from conducting trials in a safe and effective manner analyzing and interpreting the data to a forward looking assessment and discussion of regulatory issues impacting domestic international and global clinical trials Considered by many as the gold standard reference on oncology clinical trials in the field the second edition continues to provide examples of real life flaws and real world examples for how to successfully design conduct and analyze quality clinical trials and interpret them With chapters written by oncologists researchers biostatisticians clinical research administrators and industry and FDA representatives this volume provides a comprehensive guide in the design conduct monitoring analysis and reporting of clinical trials in oncology NEW TO THIS EDITION Outlines



how to design clinical trials with and without biomarker testing including genomics based basket trials and adaptive trials for all phases during treatment and quality of life trials Includes new chapters on immunotherapy trials radiation therapy trials multi arm trials meta analysis and adaptive design use of genomics dose modifications and use of ancillary treatments in investigational studies establishing surrogate endpoints practical issues with correlative studies cost effectiveness analysis and more Comprehensively covers all regulatory aspects in the pursuit of global oncology trials Digital access to the ebook included *Applied Meta-Analysis with R* Ding-Geng (Din) Chen,Karl E. Peace,2013-05-03 In biostatistical research and

courses practitioners and students often lack a thorough understanding of how to apply statistical methods to synthesize biomedical and clinical trial data Filling this knowledge gap *Applied Meta Analysis with R* shows how to implement statistical meta analysis methods to real data using R Drawing on their extensive research and teaching experiences the authors provide detailed step by step explanations of the implementation of meta analysis methods using R Each chapter gives examples of real studies compiled from the literature After presenting the data and necessary background for understanding the applications various methods for analyzing meta data are introduced The authors then develop analysis code using the appropriate R packages and functions This systematic approach helps readers thoroughly understand the analysis methods and R implementation enabling them to use R and the methods to analyze their own meta data Suitable as a graduate level text for a meta data analysis course the book is also a valuable reference for practitioners and biostatisticians even those with little or no experience in using R in public health medical research governmental agencies and the pharmaceutical industry **Confidence Intervals for Proportions and Related Measures of Effect Size** Robert Gordon

Newcombe,2012-08-25 *Confidence Intervals for Proportions and Related Measures of Effect Size* illustrates the use of effect size measures and corresponding confidence intervals as more informative alternatives to the most basic and widely used significance tests The book provides you with a deep understanding of what happens when these statistical methods are applied **Clinical Trial Data Analysis Using R and SAS** Ding-Geng (Din) Chen,Karl E. Peace,Pinggao Zhang,2017-06-01

Review of the First Edition The goal of this book as stated by the authors is to fill the knowledge gap that exists between developed statistical methods and the applications of these methods Overall this book achieves the goal successfully and does a nice job I would highly recommend it The example based approach is easy to follow and makes the book a very helpful desktop reference for many biostatistics methods *Journal of Statistical Software Clinical Trial Data Analysis Using R and SAS Second Edition* provides a thorough presentation of biostatistical analyses of clinical trial data with step by step implementations using R and SAS The book s practical detailed approach draws on the authors 30 years experience in biostatistical research and clinical development The authors develop step by step analysis code using appropriate R packages and functions and SAS PROCs which enables readers to gain an understanding of the analysis methods and R and SAS implementation so that they can use these two popular software packages to analyze their own clinical trial data What s New

in the Second Edition Adds SAS programs along with the R programs for clinical trial data analysis Updates all the statistical analysis with updated R packages Includes correlated data analysis with multivariate analysis of variance Applies R and SAS to clinical trial data from hypertension duodenal ulcer beta blockers familial adenomatous polyposis and breast cancer trials Covers the biostatistical aspects of various clinical trials including treatment comparisons time to event endpoints longitudinal clinical trials and bioequivalence trials

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### **Clinical Trial Methodology Chapman Hallcrc Biostatistics Series Introduction**

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