

Chapman & Hall/CRC Biostatistics Series

Adaptive Design Methods in Clinical Trials

Second Edition

**Shein-Chung Chow
Mark Chang**



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Adaptive Design Methods In Clinical Trials Second Edition Chapman Hallcrc Biostatistics Series

**Alex Dmitrienko,Ajit C. Tamhane, Frank
Bretz**



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With new statistical and scientific issues arising in adaptive clinical trial design including the U S FDA s recent draft guidance a new edition of one of the first books on the topic is needed Adaptive Design Methods in Clinical Trials Second Edition reflects recent developments and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

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 Adapti

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

Optimal Design for Nonlinear Response Models Valerii V. Fedorov, Sergei L. Leonov, 2013-07-15 Optimal Design for Nonlinear Response Models discusses the theory and applications of model based experimental design with a strong emphasis on biopharmaceutical studies The book draws on the authors many years of experience in academia and the pharmaceutical industry While the focus is on nonlinear models the book begins with an explanation of the key ideas using linear models as examples Applying the linearization in the parameter space it then covers nonlinear models and locally optimal designs as well as minimax optimal on average and Bayesian designs The authors also discuss adaptive designs focusing on procedures with non informative stopping The common goals of experimental design such as reducing costs supporting efficient decision making and gaining maximum information under various constraints are often the same across diverse applied areas Ethical and regulatory aspects play a much more prominent role in biological medical and pharmaceutical research The authors address all of these issues through many examples in the book

Statistical Design and Analysis of Stability Studies

Shein-Chung Chow, 2007-05-30 The US Food and Drug Administration's Report to the Nation in 2004 and 2005 indicated that one of the top reasons for drug recall was that stability data did not support existing expiration dates. Pharmaceutical companies conduct stability studies to characterize the degradation of drug products and to estimate drug shelf life. Illustrating how stability data can be used to estimate drug shelf life.

Biostatistics: A Computing Approach Stewart Anderson, 2011-12-20 The emergence of high speed computing has facilitated the development of many exciting statistical and mathematical methods in the last 25 years broadening the landscape of available tools in statistical investigations of complex data. *Biostatistics: A Computing Approach* focuses on visualization and computational approaches associated with both modern and classical techniques. Furthermore it promotes computing as a tool for performing both analyses and simulations that can facilitate such understanding. As a practical matter programs in R and SAS are presented throughout the text. In addition to these programs appendices describing the basic use of SAS and R are provided. Teaching by example this book emphasizes the importance of simulation and numerical exploration in a modern day statistical investigation. A few statistical methods that can be implemented with simple calculations are also worked into the text to build insight about how the methods really work. Suitable for students who have an interest in the application of statistical methods but do not necessarily intend to become statisticians this book has been developed from *Introduction to Biostatistics II* which the author taught for more than a decade at the University of Pittsburgh.

Essentials of a Successful Biostatistical Collaboration Arul Earnest, 2016-10-14 The aim of this book is to equip biostatisticians and other quantitative scientists with the necessary skills, knowledge and habits to collaborate effectively with clinicians in the healthcare field. The book provides valuable insight on where to look for information and material on sample size and statistical techniques commonly used in clinical research and on how best to communicate with clinicians. It also covers the best practices to adopt in terms of project time and data management relationship with collaborators etc.

Multiple Testing Problems in Pharmaceutical Statistics Alex Dmitrienko, Ajit C. Tamhane, Frank Bretz, 2009-12-08 Useful Statistical Approaches for Addressing Multiplicity Issues. Includes practical examples from recent trials. Bringing together leading statisticians, scientists and clinicians from the pharmaceutical industry, academia and regulatory agencies. *Multiple Testing Problems in Pharmaceutical Statistics* explores the rapidly growing area of multiple comparison research with an emphasis on pharmaceutical applications. In each chapter the expert contributors describe important multiplicity problems encountered in pre-clinical and clinical trial settings. The book begins with a broad introduction from a regulatory perspective to different types of multiplicity problems that commonly arise in confirmatory controlled clinical trials before giving an overview of the concepts, principles and procedures of multiple testing. It then presents statistical methods for analyzing clinical dose response studies that compare several dose levels with a control as well as statistical methods for analyzing multiple endpoints in clinical trials. After covering gatekeeping procedures for testing hierarchically ordered hypotheses the book discusses statistical approaches for the design and analysis of adaptive

designs and related confirmatory hypothesis testing problems The final chapter focuses on the design of pharmacogenomic studies based on established statistical principles It also describes the analysis of data collected in these studies taking into account the numerous multiplicity issues that occur This volume explains how to solve critical issues in multiple testing encountered in pre clinical and clinical trial applications It presents the necessary statistical methodology along with examples and software code to show how to use the methods in practice

Mixed Effects Models for the Population Approach Marc Lavielle, 2014-07-14 Wide Ranging Coverage of Parametric Modeling in Linear and Nonlinear Mixed Effects Models Mixed Effects Models for the Population Approach Models Tasks Methods and Tools presents a rigorous framework for describing implementing and using mixed effects models With these models readers can perform parameter estimation and modeling across a whole population of individuals at the same time Easy to Use Techniques and Tools for Real World Data Modeling The book first shows how the framework allows model representation for different data types including continuous categorical count and time to event data This leads to the use of generic methods such as the stochastic approximation of the EM algorithm SAEM for modeling these diverse data types The book also covers other essential methods including Markov chain Monte Carlo MCMC and importance sampling techniques The author uses publicly available software tools to illustrate modeling tasks Methods are implemented in Monolix and models are visually explored using Mlxplore and simulated using Simulx Careful Balance of Mathematical Representation and Practical Implementation This book takes readers through the whole modeling process from defining creating a parametric model to performing tasks on the model using various mathematical methods Statisticians and mathematicians will appreciate the rigorous representation of the models and theoretical properties of the methods while modelers will welcome the practical capabilities of the tools The book is also useful for training and teaching in any field where population modeling occurs

Survival Analysis in Medicine and Genetics Jialiang Li, Shuangge Ma, 2013-06-04 Using real data sets throughout this text introduces the latest methods for analyzing high dimensional survival data With an emphasis on the applications of survival analysis techniques in genetics it presents a statistical framework for burgeoning research in this area and offers a set of established approaches for statistical analysis The book reveals a new way of looking at how predictors are associated with censored survival time and extracts novel statistical genetic methods for censored survival time outcome from the vast amount of research results in genomics

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