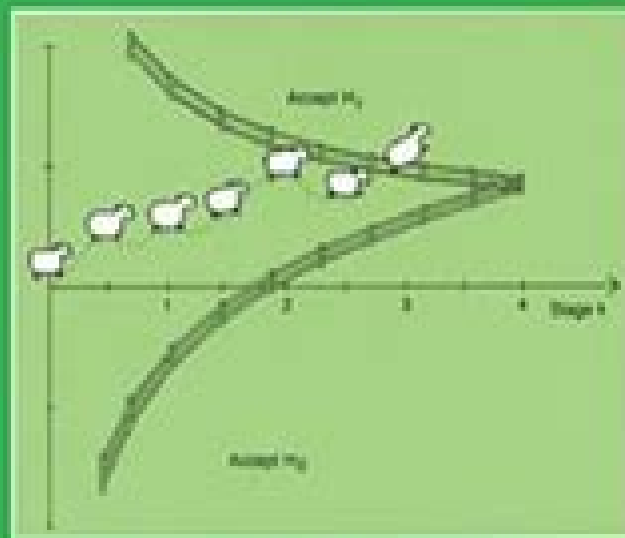


GROUP SEQUENTIAL METHODS

APPLICATIONS to CLINICAL TRIALS



Christopher Jennison
and
Bruce W Turnbull

Group Sequential Methods With Applications To Clinical Trials Chapman Hallcrc Interdisciplinary Statistics

**Christopher Jennison, Bruce W.
Turnbull**



Group Sequential Methods With Applications To Clinical Trials Chapman Hallcrc Interdisciplinary Statistics:

Group Sequential Methods with Applications to Clinical Trials Christopher Jennison, Bruce W. Turnbull, 1999-09-15 Group sequential methods answer the needs of clinical trial monitoring committees who must assess the data available at an interim analysis. These interim results may provide grounds for terminating the study effectively reducing costs or may benefit the general patient population by allowing early dissemination of its findings. Group sequential methods provide a means to balance the ethical and financial advantages of stopping a study early against the risk of an incorrect conclusion. *Group Sequential Methods with Applications to Clinical Trials* describes group sequential stopping rules designed to reduce average study length and control Type I and II error probabilities. The authors present one sided and two sided tests, introduce several families of group sequential tests and explain how to choose the most appropriate test and interim analysis schedule. Their topics include placebo controlled randomized trials, bio equivalence testing, crossover and longitudinal studies and linear and generalized linear models. Research in group sequential analysis has progressed rapidly over the past 20 years. *Group Sequential Methods with Applications to Clinical Trials* surveys and extends current methods for planning and conducting interim analyses. It provides straightforward descriptions of group sequential hypothesis tests in a form suited for direct application to a wide variety of clinical trials. Medical statisticians engaged in any investigations planned with interim analyses will find this book a useful and important tool.

Modern Adaptive Randomized Clinical Trials Oleksandr Sverdlov, 2015-06-30 Is adaptive randomization always better than traditional fixed schedule randomization? Which procedures should be used and under which circumstances? What special considerations are required for adaptive randomized trials? What kind of statistical inference should be used to achieve valid and unbiased treatment comparisons following adaptive randomization? *Statistical Issues in Drug Development* Stephen S. Senn, 2008-02-28 Drug development is the process of finding and producing therapeutically useful pharmaceuticals, turning them into safe and effective medicine and producing reliable information regarding the appropriate dosage and dosing intervals. With regulatory authorities demanding increasingly higher standards in such developments, statistics has become an intrinsic and critical element in the design and conduct of drug development programmes. *Statistical Issues in Drug Development* presents an essential and thought provoking guide to the statistical issues and controversies involved in drug development. This highly readable second edition has been updated to include comprehensive coverage of the design and interpretation of clinical trials. Expanded sections on missing data, equivalence meta analysis and dose finding. An examination of both Bayesian and frequentist methods. A new chapter on pharmacogenomics and expanded coverage of pharmaco epidemiology and pharmaco economics. Coverage of the ICH guidelines in particular ICH E9. *Statistical Principles for Clinical Trials* It is hoped that the book will stimulate dialogue between statisticians and life scientists working within the pharmaceutical industry. The accessible and wide ranging coverage make it essential reading for both statisticians and non statisticians working in the pharmaceutical industry, regulatory bodies.

and medical research institutes There is also much to benefit undergraduate and postgraduate students whose courses include a medical statistics component *Principles and Practice of Clinical Research* John I. Gallin, Frederick P

Ognibene, 2012-05-31 This expanded third edition provides an introduction to the conduct of clinical research as well as more comprehensive and expansive content about the infrastructure necessary for a successful clinical research organization or enterprise With authors who are experts in clinical research in both the public and private sectors this publication provides essential information to clinical investigators who wish to develop and conduct well designed patient based research protocols that comply with rigorous study design ethical and regulatory requirements **Principles and Practice of**

Emergency Research Response Robert A. Sorenson, 2024-08-31 Unlocking the Future of Infectious Disease Research Response In a world where emerging infectious diseases constantly threaten humanity advances in science and technology promise defense against future pathogens before they cause pandemics The field of emergency research response and preparedness remains in its infancy however Not until the 2014 West African Ebola outbreak was accelerated research broadly recognized as a crucial component of emergency response Many outbreaks and one global pandemic later it is clear the world must be prepared to launch accelerated research responses to prevent or mitigate infectious disease outbreaks epidemics and pandemics Yet this nascent field is rife with critical scientific ethical and policy questions How can local national and global systems collaborate across disciplines and political boundaries to protect health security How can we conduct rigorous research in fragile or failed nation states What is needed for equitable distribution of vaccines and therapeutic medicines in short supply How can we accelerate trials of vaccines and therapeutics during an emergency without compromising scientific rigor or ethical standards How do we integrate communities and stakeholders into research preparedness and response The editors bring decades of experience to their collaboration with renowned research scientists and health policy experts Together they have crafted a compendium that proposes normative standards and offers practical guidance for preparedness and rapid research response This pioneering open access textbook presents principles and practices forged from experience in health emergencies insights that illuminate a path forward for research response and preparedness The goal is to stop outbreaks from becoming avoidable pandemics and to mitigate illness death and social disruption if they cannot be stopped *Principles and Practice of Emergency Research Response* merges historical understanding with insights into possible futures It will serve as an indispensable compass for curtailing infectious disease threats through research global health policy changes and research capacity improvements where they are most needed The editors hope that this book will be an ongoing reference for governments health organizations development agencies researchers policy experts ethicists and social scientists To facilitate focused and enhanced learning it incorporates pedagogical tools such as abstracts learning objectives discussion questions real life examples and learning tracks Robust global health security requires effective preparation for and response to emerging and re emerging pathogens This volume

should help guide us towards a more resilient future

Bayesian Psychometric Modeling Roy Levy, Robert J.

Mislevy, 2017-07-28 A Single Cohesive Framework of Tools and Procedures for Psychometrics and Assessment Bayesian Psychometric Modeling presents a unified Bayesian approach across traditionally separate families of psychometric models It shows that Bayesian techniques as alternatives to conventional approaches offer distinct and profound advantages in achieving many goals of psychometrics Adopting a Bayesian approach can aid in unifying seemingly disparate and sometimes conflicting ideas and activities in psychometrics This book explains both how to perform psychometrics using Bayesian methods and why many of the activities in psychometrics align with Bayesian thinking The first part of the book introduces foundational principles and statistical models including conceptual issues normal distribution models Markov chain Monte Carlo estimation and regression Focusing more directly on psychometrics the second part covers popular psychometric models including classical test theory factor analysis item response theory latent class analysis and Bayesian networks Throughout the book procedures are illustrated using examples primarily from educational assessments A supplementary website provides the datasets WinBUGS code R code and Netica files used in the examples

Group Sequential and Confirmatory Adaptive Designs in Clinical Trials Gernot Wassmer, Werner Brannath, 2016-07-04 This book provides an up to date review of the general principles of and techniques for confirmatory adaptive designs Confirmatory adaptive designs are a generalization of group sequential designs With these designs interim analyses are performed in order to stop the trial prematurely under control of the Type I error rate In adaptive designs it is also permissible to perform a data driven change of relevant aspects of the study design at interim stages This includes for example a sample size reassessment a treatment arm selection or a selection of a pre specified sub population Essentially this adaptive methodology was introduced in the 1990s Since then it has become popular and the object of intense discussion and still represents a rapidly growing field of statistical research This book describes adaptive design methodology at an elementary level while also considering designing and planning issues as well as methods for analyzing an adaptively planned trial This includes estimation methods and methods for the determination of an overall p value Part I of the book provides the group sequential methods that are necessary for understanding and applying the adaptive design methodology supplied in Parts II and III of the book The book contains many examples that illustrate use of the methods for practical application The book is primarily written for applied statisticians from academia and industry who are interested in confirmatory adaptive designs It is assumed that readers are familiar with the basic principles of descriptive statistics parameter estimation and statistical testing This book will also be suitable for an advanced statistical course for applied statisticians or clinicians with a sound statistical background

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 bio statistics epidemiology medicine pharmacy and public health

Group Sequential and Adaptive Methods for Clinical Trials, Second Edition Christopher Jennison, Bruce W. Turnbull, 2008-03

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

Group Sequential and Adaptive Methods Carl Fredrik Ohn, 2011

Group-Sequential Clinical Trials with Multiple Co-Objectives Toshimitsu Hamasaki, Koko Asakura, Scott R. Evans, Toshimitsu Ochiai, 2016-06-01 This book focuses on group sequential methods for clinical trials with co primary endpoints based on the decision making frameworks for 1 rejecting the null hypothesis stopping for efficacy 2 rejecting the alternative hypothesis stopping for futility and 3 rejecting the null or alternative hypothesis stopping for either futility or efficacy where the trial is designed to evaluate whether the intervention is superior to the control on all endpoints For assessing futility there are two fundamental approaches i e the decision to stop for futility based on the conditional probability of rejecting the null hypothesis and the other based on stopping boundaries using group sequential methods In this book the latter approach is discussed The book also briefly deals with the group sequential methods for clinical trials designed to evaluate whether the intervention is superior to the control on at least one endpoint In addition the book describes sample size recalculation and the resulting effect on power and type I error rate The book also describes group sequential strategies for three arm clinical trials to demonstrate the non inferiority of experimental intervention to actively control and to assess the assay sensitivity to placebo control

Introduction to Statistical Methods for Clinical Trials Thomas D. Cook, David L. DeMets, 2007-11-19 This text provides a solid understanding of the various statistical topics

relevant to the design monitoring and analysis of a clinical trial It covers basic experimental design sample size randomization procedures interim and survival analyses quality of life assessment and longitudinal methods The book describes all phases of a clinical trial and explores the advantages of and objections to the intent to treat principle as well as its implementation With exercises at the end of most chapters it also illustrates methods using examples with real data from a variety of disease areas including heart and lung diseases cancer and AIDS

Sequential Experimentation in Clinical Trials Jay Bartroff, Tze Leung Lai, Mei-Chiung Shih, 2012-12-12 Sequential Experimentation in Clinical Trials Design and Analysis is developed from decades of work in research groups statistical pedagogy and workshop participation Different parts of the book can be used for short courses on clinical trials translational medical research and sequential experimentation The authors have successfully used the book to teach innovative clinical trial designs and statistical methods for Statistics Ph D students at Stanford University There are additional online supplements for the book that include chapter specific exercises and information Sequential Experimentation in Clinical Trials Design and Analysis covers the much broader subject of sequential experimentation that includes group sequential and adaptive designs of Phase II and III clinical trials which have attracted much attention in the past three decades In particular the broad scope of design and analysis problems in sequential experimentation clearly requires a wide range of statistical methods and models from nonlinear regression analysis experimental design dynamic programming survival analysis resampling and likelihood and Bayesian inference The background material in these building blocks is summarized in Chapter 2 and Chapter 3 and certain sections in Chapter 6 and Chapter 7 Besides group sequential tests and adaptive designs the book also introduces sequential change point detection methods in Chapter 5 in connection with pharmacovigilance and public health surveillance Together with dynamic programming and approximate dynamic programming in Chapter 3 the book therefore covers all basic topics for a graduate course in sequential analysis designs

Group Sequential Methods for Bivariate Survival Data in Clinical Trials: a Proposed Analytic Method S. R. Munoz, 1994

Handbook of Statistical Methods for Randomized Controlled Trials KyungMann Kim, Frank Bretz, Ying Kuen K. Cheung, Lisa V. Hampson, 2021-08-23 Statistical concepts provide scientific framework in experimental studies including randomized controlled trials In order to design monitor analyze and draw conclusions scientifically from such clinical trials clinical investigators and statisticians should have a firm grasp of the requisite statistical concepts The Handbook of Statistical Methods for Randomized Controlled Trials presents these statistical concepts in a logical sequence from beginning to end and can be used as a textbook in a course or as a reference on statistical methods for randomized controlled trials Part I provides a brief historical background on modern randomized controlled trials and introduces statistical concepts central to planning monitoring and analysis of randomized controlled trials Part II describes statistical methods for analysis of different types of outcomes and the associated statistical distributions used in testing the statistical hypotheses regarding the clinical questions Part III describes some of the most

used experimental designs for randomized controlled trials including the sample size estimation necessary in planning Part IV describe statistical methods used in interim analysis for monitoring of efficacy and safety data Part V describe important issues in statistical analyses such as multiple testing subgroup analysis competing risks and joint models for longitudinal markers and clinical outcomes Part VI addresses selected miscellaneous topics in design and analysis including multiple assignment randomization trials analysis of safety outcomes non inferiority trials incorporating historical data and validation of surrogate outcomes

Applied Sequential Methodologies Nitish Mukhopadhyay, Sujay Datta, Saibal Chattopadhyay, 2004-01-28 A technically precise yet clear presentation of modern sequential methodologies having immediate applications to practical problems in the real world Applied Sequential Methodologies communicates invaluable techniques for data mining agricultural science genetics computer simulation finance clinical trials sonar signal detection randomization

One-sided Group Sequential Procedures for Clinical Trials Ho, Chih-Hsiang, 1986 Statistical Methods for Clinical Trials Mark X. Norleans, 2000-11-08 Summarizes graphical analysis analysis of variance meta analysis and design of comparable treatment groups Streamlines the analytical techniques for continuous categorical longitudinal and survival data focusing on generalized linear models GEEs and mixed linear models and highlights p value and more

Sample Size Calculations in Clinical Research Shein-Chung Chow, Jun Shao, Hansheng Wang, Yuliya Lokhnygina, 2017-08-15 Praise for the Second Edition this is a useful comprehensive compendium of almost every possible sample size formula The strong organization and carefully defined formulae will aid any researcher designing a study Biometrics This impressive book contains formulae for computing sample size in a wide range of settings One sample studies and two sample comparisons for quantitative binary and time to event outcomes are covered comprehensively with separate sample size formulae for testing equality non inferiority and equivalence Many less familiar topics are also covered Journal of the Royal Statistical Society

Sample Size Calculations in Clinical Research Third Edition presents statistical procedures for performing sample size calculations during various phases of clinical research and development A comprehensive and unified presentation of statistical concepts and practical applications this book includes a well balanced summary of current and emerging clinical issues regulatory requirements and recently developed statistical methodologies for sample size calculation Features

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Introduction

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