

GROUP SEQUENTIAL METHODS with APPLICATIONS to CLINICAL TRIALS



Christopher Jennison
and
Bruce W. Turnbull

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Group Sequential Methods With Applications To Clinical Trials

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Group Sequential Methods With Applications To Clinical Trials:

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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 Methods and Applications of Statistics in Clinical Trials, Volume 2 Narayanaswamy Balakrishnan, 2014-06-16 Methods and Applications of Statistics in Clinical Trials Volume 2 Planning Analysis and Inferential Methods includes updates of established literature from the Wiley Encyclopedia of Clinical Trials as well as original material based on the latest developments in clinical trials Prepared by a leading expert the second volume includes numerous contributions from current prominent experts in the field of medical research In addition the volume features Multiple new articles exploring emerging topics such as evaluation methods with threshold empirical likelihood methods nonparametric ROC analysis over and under dispersed models and multi armed bandit problems Up to date research on the Cox proportional hazard model frailty models trial reports intrarater reliability conditional power and the kappa index Key qualitative issues including cost effectiveness analysis publication bias and regulatory issues which are crucial to the planning and data management of clinical trials Group Sequential and Adaptive Methods Carl Fredrik Ohn, 2011 Methods and Applications of Statistics in Clinical Trials, Volume 1 Narayanaswamy Balakrishnan, 2014-03-05 A complete guide to the key statistical concepts essential for the design and construction of clinical trials As the newest major resource in the field of medical research Methods and Applications of Statistics in Clinical Trials Volume 1 Concepts Principles Trials and Designs presents a timely and authoritative review of the central statistical concepts used to build clinical trials that obtain the best results The reference unveils modern approaches vital to understanding creating and evaluating data obtained throughout the various stages of clinical trial design and analysis Accessible and comprehensive the first volume in a two part set includes newly written articles as well as established literature from the Wiley Encyclopedia of Clinical Trials Illustrating a variety of statistical concepts and principles such as longitudinal data missing data covariates biased coin randomization repeated measurements and simple randomization the book also provides in depth coverage of the

various trial designs found within phase I IV trials Methods and Applications of Statistics in Clinical Trials Volume 1 Concepts Principles Trials and Designs also features Detailed chapters on the type of trial designs such as adaptive crossover group randomized multicenter non inferiority non randomized open labeled preference prevention and superiority trials Over 100 contributions from leading academics researchers and practitioners An exploration of ongoing cutting edge clinical trials on early cancer and heart disease mother to child human immunodeficiency virus transmission trials and the AIDS Clinical Trials Group Methods and Applications of Statistics in Clinical Trials Volume 1 Concepts Principles Trials and Designs is an excellent reference for researchers practitioners and students in the fields of clinical trials pharmaceuticals biostatistics medical research design biology biomedicine epidemiology and public health

Biopharmaceutical Sequential Statistical Applications Karl E. Peace, 1992-03-25 Focusing on group sequential procedures summarizes the sequential statistical methods used in anticancer antiviral cardiovascular and gastrointestinal drug research and screening The clinical and preclinical applications are mainly presented as case studies many of which form part of New Drug **Handbook of Multiple Comparisons** Xinping Cui, Thorsten Dickhaus, Ying Ding, Jason C. Hsu, 2021-11-17 Written by experts that include originators of some key ideas chapters in the Handbook of Multiple Testing cover multiple comparison problems big and small with guidance toward error rate control and insights on how principles developed earlier can be applied to current and emerging problems Some highlights of the coverages are as follows Error rate control is useful for controlling the incorrect decision rate Chapter 1 introduces Tukey's original multiple comparison error rates and point to how they have been applied and adapted to modern multiple comparison problems as discussed in the later chapters Principles endure While the closed testing principle is more familiar Chapter 4 shows the partitioning principle can derive confidence sets for multiple tests which may become important as the profession goes beyond making decisions based on p values Multiple comparisons of treatment efficacy often involve multiple doses and endpoints Chapter 12 on multiple endpoints explains how different choices of endpoint types lead to different multiplicity adjustment strategies while Chapter 11 on the MCP Mod approach is particularly useful for dose finding To assess efficacy in clinical trials with multiple doses and multiple endpoints the reader can see the traditional approach in Chapter 2 the Graphical approach in Chapter 5 and the multivariate approach in Chapter 3 Personalized precision medicine based on targeted therapies already a reality naturally leads to analysis of efficacy in subgroups Chapter 13 draws attention to subtle logical issues in inferences on subgroups and their mixtures with a principled solution that resolves these issues This chapter has implication toward meeting the ICH E9 R1 Estimands requirement Besides the mere multiple testing methodology itself the handbook also covers related topics like the statistical task of model selection in Chapter 7 or the estimation of the proportion of true null hypotheses or in other words the signal prevalence in Chapter 8 It also contains decision theoretic considerations regarding the admissibility of multiple tests in Chapter 6 The issue of selected inference is addressed in Chapter 9 Comparison of responses can involve millions of voxels in

medical imaging or SNPs in genome wide association studies GWAS Chapter 14 and Chapter 15 provide state of the art methods for large scale simultaneous inference in these settings

Methods and Applications of Statistics in the Life and Health Sciences Narayanaswamy Balakrishnan, 2009-12-02 Inspired by the Encyclopedia of Statistical Sciences Second Edition this volume outlines the statistical tools for successfully working with modern life and health sciences research Data collection holds an essential part in dictating the future of health sciences and public health as the compilation of statistics allows researchers and medical practitioners to monitor trends in health status identify health problems and evaluate the impact of health policies and programs Methods and Applications of Statistics in the Life and Health Sciences serves as a single one of a kind resource on the wide range of statistical methods techniques and applications that are applied in modern life and health sciences in research Specially designed to present encyclopedic content in an accessible and self contained format this book outlines thorough coverage of the underlying theory and standard applications to research in related disciplines such as biology epidemiology clinical trials and public health Uniquely combining established literature with cutting edge research this book contains classical works and more than twenty five new articles and completely revised contributions from the acclaimed Encyclopedia of Statistical Sciences Second Edition The result is a compilation of more than eighty articles that explores classic methodology and new topics including Sequential methods in biomedical research Statistical measures of human quality of life Change point methods in genetics Sample size determination for clinical trials Mixed effects regression models for predicting pre clinical disease Probabilistic and statistical models for conception Statistical methods are explored and applied to population growth disease detection and treatment genetic and genomic research drug development clinical trials screening and prevention and the assessment of rehabilitation recovery and quality of life These topics are explored in contributions written by more than 100 leading academics researchers and practitioners who utilize various statistical practices such as election bias survival analysis missing data techniques and cluster analysis for handling the wide array of modern issues in the life and health sciences With its combination of traditional methodology and newly developed research Methods and Applications of Statistics in the Life and Health Sciences has everything students academics and researchers in the life and health sciences need to build and apply their knowledge of statistical methods and applications

Multiple Sclerosis Therapeutics Jeffrey A. Cohen, Richard A. Rudick, 2011-10-20 This book comprehensively reviews the current state of clinical trial methods in multiple sclerosis treatment providing investigators sponsors and specialists with current knowledge of outcome measures and study designs for disease and symptom management The status of the rapidly evolving field of disease modifying drugs is presented with emphasis on the most promising therapies currently being tested Experts discuss disease and symptom management for MS subtypes including neuromyelitis optica and pediatric MS In addition key scientific advances in MS pathology genetics immunology and epidemiology are presented The fourth edition has been extensively revised featuring more than 50% new material All chapters have been substantially updated to

provide current information on rapidly evolving topics and this volume contains 15 new chapters reflecting the growth of the field in recent years This book is an essential reference for practitioners caring for MS patients investigators planning or conducting clinical trials and clinical trial sponsors Data Monitoring Committees in Clinical Trials Susan S.

Ellenberg, Thomas R. Fleming, David L. DeMets, 2019-04-01 The authoritative guide for Data Monitoring Committees fully revised and updated The number of clinical trials sponsored by government agencies and pharmaceutical companies has grown in recent years prompting an increased need for interim monitoring of data on safety and efficacy Data Monitoring Committees DMCs are an essential component of many clinical trials safeguarding trial participants and protecting the credibility and validity of the study Data Monitoring Committees in Clinical Trials A Practical Perspective 2nd Edition offers practical advice for those managing and conducting clinical trials and serving on Data Monitoring Committees providing a practical overview of the establishment purpose and responsibilities of these committees Examination of topics such as the composition and independence of DMCs statistical philosophical and ethical considerations and determining when a DMC is needed presents readers with a comprehensive foundational knowledge of clinical trial oversight Providing recent examples to illustrate DMC principles this fully updated guide reflects current developments and practices in clinical trial oversight and offers expanded coverage of emerging issues and challenges in the field This new second edition covers the most current information on DMC policies issues in monitoring trials using new designs and recent trial publications relevant to DMC decision making Presents practical advice for those managing and conducting clinical trials and serving on Data Monitoring Committees Illustrates the types of challenging issues Data Monitoring Committees face in practical situations Provides updated and expanded coverage of topics including regulatory and funding agency guidelines and trial designs and their associated demands and limitations Includes a new chapter addressing legal issues that affect DMC members and discusses general litigation concerns relevant to clinical research Expands treatment of current journal publications addressing DMC issues Data Monitoring Committees in Clinical Trials A Practical Perspective 2nd Edition is a must have text for anyone engaged in DMC activities as well as trial sponsors clinical trial researchers regulatory and bioethics professionals and those associated with clinical trials in academic government and industry settings *Sample Size Calculations in Clinical Research* Shein-Chung Chow, Hansheng Wang, Jun Shao, 2003-03-04 Sample size calculation plays an important role in clinical research It is not uncommon however to observe discrepancies among study objectives or hypotheses study design statistical analysis or test statistic and sample size calculation Focusing on sample size calculation for studies conducted during the various phases of clinical resea **Biostatistics in Clinical Trials** Carol K. Redmond, Theodore Colton, 2001-04-25 The second volume in the Wiley reference series in Biostatistics Featuring articles from the prestigious Encyclopedia of Biostatistics many of which have been fully revised and updated to include recent developments Biostatistics in Clinical Trials also includes up to 25% newly commissioned material reflecting the latest thinking in Bayesian methods Benefit risk

assessment Cost effectiveness Ethics Fraud With exceptional contributions from leading experts in academia government and industry Biostatistics in Clinical Trials has been designed to complement existing texts by providing extensive up to date coverage and introducing the reader to the research literature Offering comprehensive coverage of all aspects of clinical trials Biostatistics in Clinical Trials Includes concise definitions and introductions to numerous concepts found in current literature Discusses the software and textbooks available Uses extensive cross references helping to facilitate further research and enabling the reader to locate definitions and related concepts Biostatistics in Clinical Trials offers both academics and practitioners from various disciplines and settings such as universities the pharmaceutical industry and clinical research organisations up to date information as well as references to assist professionals involved in the design and conduct of clinical trials

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

Practical Considerations for Adaptive Trial Design and Implementation Weili He, José Pinheiro, Olga M. Kuznetsova, 2014-10-15 This edited volume is a definitive text on adaptive clinical trial designs from creation and customization to utilization As this book covers the full spectrum of topics involved in the adaptive designs arena it will serve as a valuable reference for researchers working in industry government and academia The target audience is anyone involved in the planning and execution of clinical trials in particular statisticians clinicians pharmacometricians clinical operation specialists drug supply managers and infrastructure providers In spite of the increased efficiency of adaptive trials in saving costs and time ultimately getting drugs to patients sooner their adoption in clinical development is still relatively low One of the chief reasons is the higher complexity of adaptive design trials as compared to traditional trials Barriers to the use of clinical trials with adaptive features include the concerns about the integrity of study design and

conduct the risk of regulatory non acceptance the need for an advanced infrastructure for complex randomization and clinical supply scenarios change management for process and behavior modifications extensive resource requirements for the planning and design of adaptive trials and the potential to relegate key decision makings to outside entities There have been limited publications that address these practical considerations and recommend best practices and solutions This book fills this publication gap providing guidance on practical considerations for adaptive trial design and implementation The book comprises three parts Part I focuses on practical considerations from a design perspective whereas Part II delineates practical considerations related to the implementation of adaptive trials Putting it all together Part III presents four illustrative case studies ranging from description and discussion of specific adaptive trial design considerations to the logistic and regulatory issues faced in trial implementation Bringing together the expertise of leading key opinion leaders from pharmaceutical industry academia and regulatory agencies this book provides a balanced and comprehensive coverage of practical considerations for adaptive trial design and implementation *Oncology Clinical Trials* Susan Halabi,William Kevin Kelly,2009-12-22 Clinical trials are the engine of progress in the development of new drugs and devices for the detection monitoring prevention and treatment of cancer A well conceived carefully designed and efficiently conducted clinical trial can produce results that change clinical practice overnight deliver new oncology drugs and diagnostics to the marketplace and expand the horizon of contemporary thinking about cancer biology A poorly done trial does little to advance the field or guide clinical practice consumes precious clinical and financial resources and challenges the validity of the ethical contract between investigators and the volunteers who willingly give their time and effort to benefit future patients With chapters written by oncologists researchers biostatisticians clinical research administrators and industry and FDA representatives *Oncology Clinical Trials* provides a comprehensive guide for both early career and senior oncology investigators into the successful design conduct and analysis of an oncology clinical trial *Oncology Clinical Trials* covers how to formulate a study question selecting a study population study design of Phase I II and III trials toxicity monitoring data analysis and reporting use of genomics cost effectiveness analysis systemic review and meta analysis and many other issues Many examples of real life flaws in clinical trials that have been reported in the literature are included throughout The book discusses clinical trials from start to finish focusing on real life examples in the development design and analysis of clinical trials *Oncology Clinical Trials* features A systematic guide to all aspects of the design conduct analysis and reporting of clinical trials in oncology Contributions from oncologists researchers biostatisticians clinical research administrators and industry and FDA representatives Hot topics in oncology trials including multi arm trials meta analysis and adaptive design use of genomics and cost effectiveness analysis Real life examples from reported clinical trials included throughout *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

Planning and Analyzing Clinical Trials with Composite Endpoints Geraldine Rauch,Svenja Schöler,Meinhard Kieser,2018-05-22 This book addresses the most important aspects of how to plan and evaluate clinical trials with a composite primary endpoint to guarantee a clinically meaningful and valid interpretation of the results Composite endpoints are often used as primary efficacy variables for clinical trials particularly in the fields of oncology and cardiology These endpoints combine several variables of interest within a single composite measure and as a result all variables that are of major clinical relevance can be considered in the primary analysis without the need to adjust for multiplicity Moreover composite endpoints are intended to increase the size of the expected effects thus making clinical trials more powerful The book offers practical advice for statisticians and medical experts involved in the planning and analysis of clinical trials For readers who are mainly interested in the application of the methods all the approaches are illustrated with real world clinical trial examples and the software codes required for fast and easy implementation are provided The book also discusses all the methods in the context of relevant guidelines related to the topic To benefit most from the book readers should be familiar with the principles of clinical trials and basic statistical methods

Biostatistics in Biopharmaceutical Research and Development Ding-Geng Chen,2024-12-24 The Deming Conference on Applied Statistics has long been deemed an influential event in the biostatistics and biopharmaceutical profession It provides learning experience on recent developments in statistical methodologies in biopharmaceutical applications and FDA regulations This book honors 80 years of contributions and dedication of the Deming Conference in biostatistics and biopharmaceutical clinical trial methodology and applications All chapters are contributed by world class and prominent Deming speakers who ve contributed their

cutting edge research and developments to the community Volume 1 covers Historical Milestones in Clinical Trial Design FDA biopharmaceutical design guidance and emerging development in Clinical Trial Design Methodology This book aims to booster research education and training in biostatistics and in biopharmaceutical research and development Chapter Response adaptive Randomization Designs Based on Optimal Allocation Proportion is available open access under a Creative Commons Attribution 4.0 International License via link [springer.com](https://www.springer.com) *Biopharmaceutical Applied Statistics Symposium* Karl E. Peace, Ding-Geng Chen, Sandeep Menon, 2018-09-03 This BASS book Series publishes selected high quality papers reflecting recent advances in the design and biostatistical analysis of biopharmaceutical experiments particularly biopharmaceutical clinical trials The papers were selected from invited presentations at the Biopharmaceutical Applied Statistics Symposium BASS which was founded by the first Editor in 1994 and has since become the premier international conference in biopharmaceutical statistics The primary aims of the BASS are 1 to raise funding to support graduate students in biostatistics programs and 2 to provide an opportunity for professionals engaged in pharmaceutical drug research and development to share insights into solving the problems they encounter The BASS book series is initially divided into three volumes addressing 1 Design of Clinical Trials 2 Biostatistical Analysis of Clinical Trials and 3 Pharmaceutical Applications This book is the third of the 3 volume book series The topics covered include Targeted Learning of Optimal Individualized Treatment Rules under Cost Constraints Uses of Mixture Normal Distribution in Genomics and Otherwise Personalized Medicine Design Considerations Adaptive Biomarker Subpopulation and Tumor Type Selection in Phase III Oncology Trials High Dimensional Data in Genomics Synergy or Additivity The Importance of Defining the Primary Endpoint Full Bayesian Adaptive Dose Finding Using Toxicity Probability Interval TPI Alpha recycling for the Analyses of Primary and Secondary Endpoints of Clinical Trials Expanded Interpretations of Results of Carcinogenicity Studies of Pharmaceuticals Randomized Clinical Trials for Orphan Drug Development Mediation Modeling in Randomized Trials with Non normal Outcome Variables Statistical Considerations in Using Images in Clinical Trials Interesting Applications over 30 Years of Consulting Uncovering Fraud Misconduct and Other Data Quality Issues in Clinical Trials Development and Evaluation of High Dimensional Prognostic Models and Design and Analysis of Biosimilar Studies

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