

Sequential Medical Trials

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**Institute of Medicine, Board on Health
Sciences Policy, Committee on
Strategies for Small-Number-
Participant Clinical Research Trials**

Sequential Medical Trials:

The Design and Analysis of Sequential Clinical Trials John Whitehead, 1997-08-04 This book details all aspects of sequential clinical trials from preliminary planning through the monitoring of the trial to the final analysis of the results. Emphasis is placed on the triangular test and other procedures based on straight line stopping boundaries. These methods allow for frequent or occasional interim analyses and permit the analysis of a wide variety of patient responses. Alternative procedures are also covered in detail and these include spending function methods, repeated confidence intervals, and Bayesian approaches to sequential clinical trials. *Sequential Medical Trials* P. Armitage, 1980 **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 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

Sequential medical trials (stopping rules/ asymptotic optimality). STANFORD UNIV CA DEPT OF STATISTICS.,T. L. Lai,B. Levin,H. Robbins,David Siegmund,1980 A model for sequential clinical trials is discussed Three proposed stopping rules are studied by Monte Carlo for small patient horizons and mathematically for large patient horizons They are shown to be about equally effective and asymptotically optimal from both Bayesian and frequentist points of view Their advantage over any fixed sample size rule is emphasized Author *SEQUENTIAL MEDICAL TRIALS*. F. J. Anscombe,PRINCETON UNIV NJ.,1943 Fundamentals of Clinical Trials Lawrence M. Friedman,Curt D. Furberg,David L. DeMets,2010-09-09 The clinical trial is the most definitive tool for evaluation of the applicability of clinical research It represents a key research activity with the potential to improve the quality of health care and control costs through careful comparison of alternative treatments 1 It has been called on many occasions the gold st dard against which all other clinical research is measured Although many clinical trials are of high quality a careful reader of the medical literature will notice that a large number have deficiencies in design conduct analysis presentation and or interpretation of results Improvements have occurred over the past few decades but too many trials are still conducted without adequate attention to its fundamental principles Certainly numerous studies could have been upgraded if the authors had had a better understanding of the fundamentals Since the publication of the first edition of this book a large number of other texts on clinical trials have appeared most of which are indicated here 2 21 Several of them however discuss only specific issues involved in clinical trials Additionally many are no longer current The purpose of this fourth edition is to update areas in which major progress has been made since the publication of the third edition We have revised most chapters considerably and added one on ethical issues 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 Small Clinical Trials Institute of Medicine, Board on Health Sciences Policy, Committee on Strategies for Small-Number-Participant Clinical Research Trials, 2001-02-01 Clinical trials are used to elucidate the most appropriate preventive diagnostic or treatment options for individuals with a given medical condition Perhaps the most essential feature of a clinical trial is that it aims to use results based on a limited sample of research participants to see if the intervention is safe and effective or if it is comparable to a comparison treatment Sample size is a crucial component of any clinical trial A trial with a small number of research participants is more prone to variability and carries a considerable risk of failing to demonstrate the effectiveness of a given intervention when one really is present This may occur in phase I safety and pharmacologic profiles II pilot efficacy evaluation and III extensive assessment of safety and efficacy trials Although phase I and II studies may have smaller sample sizes they usually have adequate statistical power which is the committee's definition of a large trial Sometimes a trial with eight participants may have adequate statistical power statistical power being the probability of rejecting the null hypothesis when the hypothesis is false Small Clinical Trials assesses the current methodologies and the appropriate situations for the conduct of clinical trials with small sample sizes This report assesses the published literature on various strategies such as 1 meta analysis to combine disparate information from several studies including Bayesian techniques as in the confidence profile method and 2 other alternatives such as assessing therapeutic results in a single treated population e.g. astronauts by sequentially measuring whether the intervention is falling above or below a preestablished probability outcome range and meeting predefined specifications as opposed to incremental improvement **Sequential medical trials** Peter Armitage, 1967 **Clinical Trials** Curtis L. Meinert, Susan Tonascia, 1986 The definitive reference work on clinical trials this book presents a wealth of detailed practical information on the design conduct and analysis of both single center and multicenter trials No other book on clinical trials offers as much detail as Meinert does on such issues as sample size calculation stratification and randomization data systems design consent form development publication policies preparation of funding requests and reporting procedures **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

Modern Approaches to Clinical Trials Using SAS: Classical, Adaptive, and Bayesian Methods Sandeep Menon, Richard C. Zink, 2015-12-09 This book covers domains of modern clinical trial design classical group sequential adaptive and Bayesian methods applicable to and used in various phases of pharmaceutical development Written for biostatisticians pharmacometricians clinical developers and statistical programmers involved in the design analysis and interpretation of clinical trials as well as students in graduate and postgraduate programs in statistics or biostatistics it covers topics including dose response and dose escalation designs sequential methods to stop trials early for overwhelming efficacy safety or futility Bayesian designs incorporating historical data adaptive sample size re estimation and randomization to allocate subjects to effective treatments population enrichment designs Methods are illustrated using clinical trials from diverse therapeutic areas including dermatology endocrinology infectious disease neurology oncology and rheumatology

Randomization in Clinical Trials William F. Rosenberger, John M. Lachin, 2004-03-24 A unique overview that melds the concepts of conditional probability and stochastic processes into real life applications The role of randomization techniques in clinical trials has become increasingly important This comprehensive guide combines both the applied aspects of randomization in clinical trials with a probabilistic treatment of properties of randomization Taking an unabashedly non Bayesian and nonparametric approach to inference the book focuses on the linear rank test under a randomization model with added discussion on likelihood based inference as it relates to sufficiency and ancillarity Developments in stochastic processes and applied probability are also given where appropriate Intuition is stressed over mathematics but not without a clear development of the latter in the context of the former Providing a consolidated review of the field the book includes relevant and practical discussions of The benefits of randomization in terms of reduction of bias Randomization as a basis for inference Covariate adaptive and response adaptive randomization Current philosophies controversies and new developments With ample problem sets theoretical exercises and short computer simulations using SAS Randomization in Clinical Trials Theory and Practice is equally useful as a standard textbook in biostatistics graduate

programs as well as a reliable reference for biostatisticians in practice

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.

Statistics Applied to Clinical Trials Ton J. Cleophas, A.H. Zwinderman, Toine F. Cleophas, Eugene P. Cleophas, 2008-12-16 In clinical medicine, appropriate statistics has become indispensable to evaluate treatment effects. Randomized controlled trials are currently the only trials that truly provide evidence-based medicine. Evidence-based medicine has become crucial to optimal treatment of patients. We can define randomized controlled trials by using Christopher J. Bulpitt's definition: a carefully and ethically designed experiment which includes the provision of adequate and appropriate controls by a process of randomization so that precisely framed questions can be answered. The answers given by randomized controlled trials constitute at present the way how patients should be clinically managed. In the setup of such randomized trial, one of the most important issues is the statistical basis. The randomized trial will never work when the statistical grounds and analyses have not been clearly defined beforehand. All endpoints should be clearly defined in order to perform appropriate power calculations. Based on these power calculations, the exact number of available patients can be calculated in order to have a sufficient quantity of individuals to have the predefined questions answered. Therefore, every clinical physician should be capable to understand the statistical basis of well-performed clinical trials. It is therefore a great pleasure that Drs. T. J. Cleophas, A. H. Zwinderman and T. F. Cleophas have published a book on statistical analysis of clinical trials. The book entitled *Statistics Applied to Clinical Trials* is clearly written and makes complex issues in statistical analysis transparent.

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 active control and to assess the assay sensitivity to placebo control

Designs for Clinical Trials David Harrington, 2011-10-09 This book will examine current issues and controversies in the design of clinical trials including topics in adaptive and sequential designs the design of correlative genomic studies the design of studies in which missing data is anticipated Each chapter will be written by an expert conducting research in the topic of that chapter As a collection the chapters would be intended to serve as a guidance for statisticians designing trials

Sequential Medical Trials Involving Paired Data Herman Chernoff, Albert John Petkau, MASSACHUSETTS INST OF TECH CAMBRIDGE Dept. of MATHEMATICS., 1979 A continuous time version of Anscombe's formulation of the problem of comparing two treatments in the context of medical trials is considered and the Bayes sequential procedure is explicitly determined Various suboptimal procedures are proposed evaluated and compared to the optimal procedure the approximation to the optimal procedure proposed by Anscombe turns out to be surprisingly efficient Comparison with the discrete time version demonstrates that the continuous time version provides accurate approximations for clinical trials involving horizon sizes as small as 100 The optimal procedure determined here provides a design which is relevant for clinical trials involving either normal or Bernoulli responses

Author

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

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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

The Enigmatic Realm of **Sequential Medical Trials**: Unleashing the Language is Inner Magic

In a fast-paced digital era where connections and knowledge intertwine, the enigmatic realm of language reveals its inherent magic. Its capacity to stir emotions, ignite contemplation, and catalyze profound transformations is nothing lacking extraordinary. Within the captivating pages of **Sequential Medical Trials** a literary masterpiece penned by way of a renowned author, readers set about a transformative journey, unlocking the secrets and untapped potential embedded within each word. In this evaluation, we shall explore the book's core themes, assess its distinct writing style, and delve into its lasting impact on the hearts and minds of people who partake in its reading experience.

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