The Design and Analysis of Sequential Clinical Trials

Revised Second Edition

John Whitehead

STATISTICS IN PRACTICE

Series Editor
Vic Barnett

Design And Analysis Of Sequential Clinical Trials

Karen Maria Facey

Design And Analysis Of Sequential Clinical 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 *Design and Analysis of Sequential Clinical Trials* John Whitehead,1984-11-01 *Issues in the Design and Analysis of Group Sequential Clinical Trials* Gary Lyle Rosner,Harvard School of Public Health,1985 **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

Design and Analysis of Group Sequential Clinical Trials with Survival Data Hélène Boucher,Harvard School of Public Health,1996 **Design and Analysis of Clinical Trials** Shein-Chung Chow,Jen-Pei Liu,2008-12-04 Praise for the First Edition of Design and Analysis of Clinical Trials An excellent book providing a discussion of the clinical trial process from designing the study through analyzing the data and to regulatory requirement could easily be used as a classroom text to understand the process in the new drug development area Statistical Methods in Medicine A complete and balanced presentation now revised updated and expanded As the field of research possibilities expands the need for a working understanding of how to carry out clinical trials only increases New developments in the theory and practice of clinical

research include a growing body of literature on the subject new technologies and methodologies and new guidelines from the International Conference on Harmonization ICH Design and Analysis of Clinical Trials Second Edition provides both a comprehensive unified presentation of principles and methodologies for various clinical trials and a well balanced summary of current regulatory requirements This unique resource bridges the gap between clinical and statistical disciplines covering both fields in a lucid and accessible manner Thoroughly updated from its first edition the Second Edition of Design and Analysis of Clinical Trials features new topics such as Clinical trials and regulations especially those of the ICH Clinical significance reproducibility and generalizability Goals of clinical trials and target population New study designs and trial types Sample size determination on equivalence and noninferiority trials as well as comparing variabilities Also three entirely new chapters cover Designs for cancer clinical trials Preparation and implementation of a clinical protocol Data management of a clinical trial Written with the practitioner in mind the presentation assumes only a minimal mathematical and statistical background for its reader Instead the writing emphasizes real life examples and illustrations from clinical case studies as well as numerous references 280 of them new to the Second Edition to the literature Design and Analysis of Clinical Trials Second Edition will benefit academic pharmaceutical medical and regulatory scientists researchers statisticians and graduate level students in these areas by serving as a useful thorough reference source for clinical research **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 **Monte Carlo Techniques for Design and Analysis of Group Sequential Clinical Trials with Multiple Primary Endpoints** Yuanjun Shi,2001 *Design and Analysis of Sequential Clinical Trials*

Using a Markov Chain Transition Rate Model with Conditional Power Gregory Russell Pond,2008 Background There are a plethora of potential statistical designs which can be used to evaluate efficacy of a novel cancer treatment in the phase II clinical trial setting Unfortunately there is no consensus as to which design one should prefer nor even which definition of efficacy should be used and the primary endpoint conclusion can vary depending on which design is chosen It would be useful if an all encompassing methodology was possible which could evaluate all the different designs simultaneously and allow investigators an understanding of the trial results under the varying scenarios Results Finite Markov chain imbedding is shown to be useful for evaluating phase II oncology clinical trial results The R code written for evaluating the simulation study is demonstrated to be fast and useful for investigating different trial designs Further details regarding the clinical trial results are presented including the potential prolongation of stable disease of the treatment which is a potentially useful marker of efficacy for this cytostatic agent Methods Finite Markov chain imbedding is a method which can be used in phase II oncology clinical trials but has never previously been evaluated for examining phase II cancer clinical trials Simple variations to the transition matrix or end state probability definitions can be performed which allow for evaluation of multiple designs and endpoints for a single trial A computer program is written in R which allows for computation of p values and conditional power two common statistical measures used for evaluation of trial results A simulation study is performed using data arising from an actual phase II clinical trial performed recently in which the study conclusion regarding the efficacy of the potential treatment was debatable Conclusions This novel methodology may prove to be an useful investigative technique for the evaluation of phase II oncology clinical trial data Future studies which have disputable conclusions might become less controversial with the aid of finite Markov chain imbedding and the possible multiple evaluations which are now viable Better understanding of activity for a given treatment might expedite the drug development process or help distinguish active from inactive treatments **Design and Analysis of Clinical Experiments** Joseph L. Fleiss,2011-01-25 First published in 1986 this unique reference to clinical experimentation remains just as relevant today Focusing on the principles of design and analysis of studies on human subjects this book utilizes and integrates both modern and classical designs Coverage is limited to experimental comparisons of treatments or in other words clinical studies in which treatments are assigned to subjects at random *Principles and Practice of Clinical Trials* Steven Piantadosi,Curtis L. Meinert,2022-07-19 This is a comprehensive major reference work for our SpringerReference program covering clinical trials Although the core of the Work will focus on the design analysis and interpretation of scientific data from clinical trials a broad spectrum of clinical trial application areas will be covered in detail This is an important time to develop such a Work as drug safety and efficacy emphasizes the Clinical Trials process Because of an immense and growing international disease burden pharmaceutical and biotechnology companies continue to develop new drugs Clinical trials have also become extremely globalized in the past 15 years with over 225 000 international trials ongoing at this point in time Principles in Practice of Clinical Trials is truly an interdisciplinary

that will be divided into the following areas 1 Clinical Trials Basic Perspectives 2 Regulation and Oversight 3 Basic Trial Designs 4 Advanced Trial Designs 5 Analysis 6 Trial Publication 7 Topics Related Specific Populations and Legal Aspects of Clinical Trials The Work is designed to be comprised of 175 chapters and approximately 2500 pages The Work will be oriented like many of our SpringerReference Handbooks presenting detailed and comprehensive expository chapters on broad subjects The Editors are major figures in the field of clinical trials and both have written textbooks on the topic There will also be a slate of 7 8 renowned associate editors that will edit individual sections of the Reference **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 **Sequential Procedures for Clinical Trials Design, Monitoring and Analysis** Karen Maria Facey,1991 *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 Analysis of Clinical Trials Using SAS Alex Dmitrienko,Gary G. Koch,2017-07-17 Analysis of Clinical Trials Using SAS A Practical Guide Second Edition bridges the gap between modern statistical methodology and real world clinical trial applications Tutorial material and step by step instructions illustrated with examples from actual trials serve to define relevant statistical approaches describe their clinical trial applications and implement the approaches rapidly and efficiently using the power of SAS Topics reflect the International Conference on Harmonization ICH guidelines for the pharmaceutical industry and address important statistical problems encountered in clinical trials Commonly used methods are covered including dose escalation and dose finding methods that are applied in Phase I and Phase II clinical trials as well as important trial designs and analysis strategies that are employed in Phase II and Phase III clinical trials such as multiplicity adjustment data monitoring and methods for handling incomplete data This book also features recommendations from clinical trial experts and a discussion of relevant regulatory guidelines This new edition includes more examples and case studies new approaches for addressing statistical problems and the following new technological updates SAS procedures used in group sequential trials PROC SEQDESIGN and PROC SEQTEST SAS procedures used in repeated measures analysis PROC GLIMMIX and PROC GEE macros for implementing a broad range of randomization based methods in clinical trials performing complex multiplicity adjustments and investigating the design and analysis of early phase trials Phase I dose escalation trials and Phase II dose finding trials Clinical statisticians research scientists and graduate students in biostatistics will greatly benefit from the decades of clinical research experience and the ready to use SAS macros compiled in this book **Group Sequential and Confirmatory Adaptive Designs in Clinical Trials** Gernot Wassmer,Werner Brannath,2025-10-14 This book provides an up to date review of the general principles and techniques of confirmatory adaptive designs a generalization of group sequential designs With these designs interim analyses are performed in order to stop a 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 First introduced in the 1990s this popular adaptive methodology has become the focus of intense discussion and is still a rapidly growing field of statistical research The book describes adaptive design methodology at an elementary level while also considering design and planning issues It also looks at methods for analyzing an adaptively planned trial such as estimation methods and methods for determining an overall p value Part I provides the group sequential preliminaries required to understand and apply the adaptive design methodology supplied in Parts II and III Many examples are included

that illustrate the practical applications of the techniques An overview of recent developments is given and new to this edition detailed descriptions of the R commands used for the calculations are provided The R package rpact which is available on CRAN allows for the recalculation of most tables and results presented in the monograph The required knowledge of R has been kept to a minimum and an online Shiny app has been made available for rpact Primarily written for applied statisticians from academia and industry who are interested in confirmatory adaptive designs the text is also suitable for an advanced statistical course for applied statisticians or clinicians with a sound statistical background *Wiley Encyclopedia of Clinical Trials* Lisa Marie Sullivan,Joseph Massaro,2008 Here you ll find more than 500 entries from the world s leading experts in the field on the basic concepts methodologies and applications in clinical trials The range of topics includes basic statistical concepts design and analysis of clinical trials ethics regulatory issues and methodologies for clinical data management and analysis *Journal of the American Statistical Association* ,2008 **An Evaluation of Design and Inference in Special Topics of Group Sequential Procedures** Timothy Michael Skalland,2015 Randomized trials are the gold standard for the clinical assessment of a new treatment compared to a placebo or standard of care Often in clinical trials patients are accrued sequentially rather than all at once Thus the data from such a trial becomes available sequentially to the researcher Monitoring and testing the accrued data throughout a trial and making decisions based on on such tests that could terminate the trial early is called sequential testing Designing and analyzing such sequential trials has garnered much attention in the statistical literature over the last 50 years The added flexibility and benefi ts from such a trial do not come free of cost Careful considerations in the design careful monitoring of the data throughout and careful analysis of the data at the conclusion are necessary to preserve the integrity of such a sequential clinical trial This thesis will be mostly concerned with a special form of sequential testing called a group sequential procedure Such procedures have the benefi t of a reduction in expected sample size while not being burdened by continual monitoring of the data after every observation Special topics of group sequential procedures include the concepts of overrun secondary endpoints and adaptive group sequential procedures Overrun is the accrual of data after the decision to terminate the trial has been reached We investigate and compare popular approaches to the incorporation of such data into the final analysis Through a simulation study it is found that a random weighting of the p values from the data up to the termination of the trial and the overrun data based the sample sizes for such data under the Sample Mean Ordering of the outcome space leads to the shortest average con fidence intervals while maintaining the nominal coverage probability Most clinical trials are designed and evaluated using a primary endpoint for the treatment eff ect Some trials have secondary endpoints to assess either safety or additional clinical benefi ts beyond the primary outcome We consider the design and analysis of group sequential trials when both a primary and secondary endpoint are of interest Our investigations are done in the setting of a gatekeeping procedure We are able to unify and generalize global proofs to certain propositions made by other researchers when we consider testing both a

primary and secondary endpoint We further investigate secondary inference in the form of con fidence interval construction through an extensive simulation study We find that the approach of Whitehead et al 2000 outperforms existing methods for the settings considered Adaptive clinical trials seek to modify some aspect of the trial after an interim look at the data in order to improve the odds of a successful trial by the end We compare some popular choices of adaptive Phase II two stage designs and introduce a new design while evaluating operating characteristics Type I error Type II error and expected sample sizes Majority of the literature focuses on minimizing the expected sample size under the null hypothesis only Our new Quasi Symmetric n2 design seeks to substantially reduce the expected sample size under the parameter values close to the design alternative while minimally increasing expected sample size under the design null We evaluate and compare such a design to existing methods Biometry, Clinical Trials and Related Topics Tadakazu Okuno,1988

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