Sequential Medical Trials

P.Armitage

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Sequential Medical Trials

P. Armitage

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, 1960 **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 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 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 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 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

Computer Analysis of Sequential Medical Trials Xu Duan-Zheng, 1990 Sequential trial is a statistical technique used in medical trials as an alternative to classical tests of significance This work provides a collection of sequential medical trials in different designs including open restricted one and two sided qualitative and quantitative trials 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

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

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