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Randomization in Clinical Trials

Theory and Practice



William F. Rosenberger • John M. Lachin

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Ding-Geng (Din) Chen, Karl E. Peace, 2010-12-14 Too often in biostatistical research and clinical trials a knowledge gap exists between developed statistical methods and the applications of these methods Filling this gap Clinical Trial Data Analysis Using R provides a thorough presentation of biostatistical analyses of clinical trial data and shows step by step how to implement the statistical methods using R The book s practical detailed approach draws on the authors 30 years of real world experience in biostatistical research and clinical development Each chapter presents examples of clinical trials based on the authors actual experiences in clinical drug development Various biostatistical methods for analyzing the data are then identified The authors develop analysis code step by step using appropriate R packages and functions This approach enables readers to gain an understanding of the analysis methods and R implementation so that they can use R to analyze their own clinical trial data With step by step illustrations of R implementations this book shows how to easily use R to simulate and analyze data from a clinical trial It describes numerous up to date statistical methods and offers sound guidance on the processes involved in clinical trials 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 Randomised Response-Adaptive Designs in Clinical Trials Anthony C Atkinson, Atanu Biswas, 2013-12-26 Randomised Response Adaptive Designs in Clinical Trials presents methods for the randomised allocation of treatments to patients in sequential clinical trials Emphasizing the practical application of clinical trial designs the book is designed for medical and applied statisticians clinicians and statisticians in training After introducing clinical trials in drug development the authors assess a simple adaptive design for binary responses without covariates They discuss randomisation and covariate balance in normally distributed responses and cover many important response adaptive designs for binary responses The book then develops response adaptive designs for continuous and longitudinal responses optimum designs with covariates and response adaptive designs with covariates It also covers response adaptive designs that are derived by optimising an objective function subject to constraints on the variance of estimated parametric functions The concluding chapter explores future directions in the development of adaptive designs Innovative Strategies, Statistical Solutions and Simulations for Modern Clinical Trials Mark Chang, John Balser, Jim Roach, Robin Bliss, 2019-03-20 This is truly an outstanding book It brings together all of the latest research in clinical trials methodology and how it can be applied to drug development Chang et al provide applications to industry supported trials This will allow statisticians in the industry community to take these methods seriously Jay Herson Johns Hopkins University The pharmaceutical industry's approach to drug discovery and

development has rapidly transformed in the last decade from the more traditional Research and Development R D approach to a more innovative approach in which strategies are employed to compress and optimize the clinical development plan and associated timelines However these strategies are generally being considered on an individual trial basis and not as part of a fully integrated overall development program Such optimization at the trial level is somewhat near sighted and does not ensure cost time or development efficiency of the overall program This book seeks to address this imbalance by establishing a statistical framework for overall global clinical development optimization and providing tactics and techniques to support such optimization including clinical trial simulations Provides a statistical framework for achieve global optimization in each phase of the drug development process Describes specific techniques to support optimization including adaptive designs precision medicine survival endpoints dose finding and multiple testing Gives practical approaches to handling missing data in clinical trials using SAS Looks at key controversial issues from both a clinical and statistical perspective Presents a generous number of case studies from multiple therapeutic areas that help motivate and illustrate the statistical methods introduced in the book Puts great emphasis on software implementation of the statistical methods with multiple examples of software code both SAS and R It is important for statisticians to possess a deep knowledge of the drug development process beyond statistical considerations For these reasons this book incorporates both statistical and clinical medical perspectives

Statistics Applied to Clinical Trials Ton J. Cleophas, Toine F. Cleophas, Aeilko H. Zwinderman, 2006 to Clinical Trials Ton J. Cleophas, A.H. Zwinderman, Toine F. Cleophas, Eugene P. Cleophas, 2009-08-29 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 I 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 transparant The Theory of Response-Adaptive

Randomization in Clinical Trials Feifang Hu, William F. Rosenberger, 2006-09-18 Presents a firm mathematical basis for

the use of response adaptive randomization procedures in practice The Theory of Response Adaptive Randomization in Clinical Trials is the result of the authors ten year collaboration as well as their collaborations with other researchers in investigating the important questions regarding response adaptive randomization in a rigorous mathematical framework Response adaptive allocation has a long history in biostatistics literature however largely due to the disastrous ECMO trial in the early 1980s there is a general reluctance to use these procedures This timely book represents a mathematically rigorous subdiscipline of experimental design involving randomization and answers fundamental questions including How does response adaptive randomization affect power Can standard inferential tests be applied following response adaptive randomization What is the effect of delayed response Which procedure is most appropriate and how can most appropriate be quantified How can heterogeneity of the patient population be incorporated Can response adaptive randomization be performed with more than two treatments or with continuous responses The answers to these questions communicate a thorough understanding of the asymptotic properties of each procedure discussed including asymptotic normality consistency and asymptotic variance of the induced allocation Topical coverage includes The relationship between power and response adaptive randomization The general result for determining asymptotically best procedures Procedures based on urn models Procedures based on sequential estimation Implications for the practice of clinical trials Useful for graduate students in mathematics statistics and biostatistics as well as researchers and industrial and academic biostatisticians this book offers a rigorous treatment of the subject in order to find the optimal procedure to use in practice Design and Analysis of Clinical Trials Shein-Chung Chow, Jen-Pei Liu, 1998-06-23 A unique unifying treatment for statistics and science in clinical trials What sets this volume apart from the many books dealing with clinical trials is its integration of statistical and clinical disciplines Stressing communication between biostatisticians and clinical scientists this work clearly relates statistical interpretation to clinical issues arising in different stages of pharmaceutical research and development Plus the principles presented here are universal enough to be easily adapted in non biopharmaceutical settings Design and Analysis of Clinical Trials tackles concepts and methodologies It not only covers statistical basics such as uncertainty and bias design considerations such as patient selection randomization and the different types of clinical trials but also deals with various methods of data analysis group sequential procedures for interim analysis efficacy data evaluation analysis of safety data and more Throughout the book Surveys current and emerging clinical issues and newly developed statistical methods Presents a critical review of statistical methodologies in various therapeutic areas Features case studies from actual clinical trials Minimizes the mathematics involved making the material widely accessible Offers each chapter as a self contained entity Includes illustrations to highlight the text This monumental reference on all facets of clinical trials is important reading for physicians clinical and medical researchers pharmaceutical scientists clinical programmers biostatisticians and anyone involved in this burgeoning area of clinical research It can also be used as a textbook in graduate level courses in the field

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 reviewof 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 throughoutthe 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 clinicaltrials pharmaceutics biostatistics medical research design biology biomedicine epidemiology and public health

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