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Medical Uses of Statistics - John C. Bailar 2012-01-10
A new edition of the classic guide to the use of statistics inmedicine, featuring examples from articles in the New EnglandJournal of Medicine Medical Uses of Statistics has served as one of the mostinfluential works on the subject for physicians,physicians-in-training, and a myriad of healthcare experts who needa clear idea of the proper application of statistical techniques inclinical studies as well as the implications of theirinterpretation for clinical practice. This Third Editionmaintains the focus on the critical ideas, rather than themechanics, to give practitioners and students the resources theyneed to understand the statistical methods they encounter in modernmedical literature. Bringing together contributions from more than two dozendistinguished statisticians and medical doctors, this volumestresses the underlying concepts in areas such as randomizedtrials, survival analysis, genetics, linear regression,meta-analysis, and risk analysis. The Third Editionincludes: Numerous examples based on studies taken directly from the pagesof the New England Journal ofMedicine Two added chapters on statistics in genetics Two new chapters on the application of statistical methods tostudies in epidemiology New chapters on analyses of randomized trials, linearregression, categorical data analysis, meta-analysis, subgroupanalyses, and risk analysis Updated chapters on statistical thinking, crossover designs,p-values, survival analysis, and reporting research results A focus on helping readers to critically interpret publishedresults of clinical research Medical Uses of Statistics, Third Edition is a valuableresource for researchers and physicians working in anyhealth-related field. It is also an excellent supplemental book forcourses on medicine, biostatistics, and clinical research at theupper-undergraduate and graduate levels. You can also visit the NewEngland Journal of Medicine website for relatedinformation.
Survival Analysis For Economic Evaluations Alongside Clinical Trials - Extrapolation with Patient-Level Data - Latimer NR 2013

Statistical Analysis of Censored Survival Time Data in Clinical Trials - Stephan Ogenstad 1982

Survival Analysis - David Machin 2006-03-30
Well received in its first edition, Survival Analysis: A Practical Approach is completely revised to provide an accessible and practical guide to survival analysis techniques in diverse environments. Illustrated with many authentic examples, the book introduces basic statistical concepts and methods to construct survival curves, later developing them to encompass more specialised and complex models. During the years since the first edition there have been several new topics that have come to the fore and many new applications. Parallel developments in computer software programmes, used to implement these methodologies, are relied upon throughout the text to bring it up to date.
An Introduction to Survival Analysis - Joel B. Greenhouse 1990*

Modelling Survival Data in Medical Research - DAVID. COLLETT 2023
Fourth edition has new chapters on Bayesian survival analysis and use of the R software. Chapters extensively revised, expanded to add new material on topics that include methods for assessing predictive ability of a model, joint models for longitudinal and survival data, modern methods for the analysis of interval-censored survival data.
Change-point Analysis of Survival Data with Application in Clinical Trials - Xuan Chen 2009
Effects of many medical procedures appear after a time lag, when a significant change occurs in subjects' failure rate. This paper focuses on the detection and estimation of such changes which is important for the evaluation and comparison of treatments and prediction of their effects. Unlike the classical change-point model, measurements may still be identically distributed, and the change point is a parameter of their common survival function. Some of the classical change-point detection techniques can still be used but the results are different.
Advanced Survival Models - Catherine Legrand 2021-03-23
Survival data analysis is a very broad field of statistics, encompassing a large variety of methods used in a wide range of applications, and in particular in medical research. During the last twenty years, several extensions of "classical" survival models have been developed to address particular situations often encountered in practice. This book aims to gather in a single reference the most commonly used extensions, such as frailty models (in case of unobserved heterogeneity or clustered data), cure models (when a fraction of the population will not experience the event of interest), competing risk models (in case of different types of event), and joint survival models for a time-to-event endpoint and a longitudinal outcome. Features Presents state-of-the art approaches for different advanced survival models including frailty models, cure models, competing risk models and joint models for a longitudinal and a survival outcome Uses consistent notation throughout the book for the different techniques presented Explains in which situation each of these models should be used, and how they are linked to specific research questions Focuses on the understanding of the models, their implementation, and their interpretation, with an appropriate level of methodological development for masters students and applied statisticians Provides references to existing R packages and SAS procedure or macros, and illustrates the use of the main ones on real datasets This book is primarily aimed at applied statisticians and graduate students of statistics and biostatistics. It can also serve as an introductory reference for methodological researchers interested in the main extensions of classical survival analysis.
Survival Analysis - Prabhanjan Tattar 2022-07
"Survival analysis generally deals with analysis of data arising from clinical trials. Censoring, truncation, and missing data create analytical challenges and the statistical methods and inference

require novel and different approaches for analysis. Statistical properties, essentially asymptotic ones, of the estimators and tests are aptly handled in the counting process framework which is drawn from the larger arm of stochastic calculus. With explosion of data generation during the past two decades, survival data has also enlarged assuming a gigantic size. Most statistical methods developed before the millennium were based on a linear approach even in the face of complex nature of survival data. Nonparametric nonlinear methods are best envisaged in the Machine Learning school. This book attempts to cover all these aspects in a concise way. Survival Analysis offers an integrated blend of statistical methods and machine learning useful in analysis of survival data. The purpose of the offering is to give an exposure to the machine learning trends for lifetime data analysis"--

Applied Survival Analysis Using R - Dirk F. Moore 2016-05-11

Applied Survival Analysis Using R covers the main principles of survival analysis, gives examples of how it is applied, and teaches how to put those principles to use to analyze data using R as a vehicle. Survival data, where the primary outcome is time to a specific event, arise in many areas of biomedical research, including clinical trials, epidemiological studies, and studies of animals. Many survival methods are extensions of techniques used in linear regression and categorical data, while other aspects of this field are unique to survival data. This text employs numerous actual examples to illustrate survival curve estimation, comparison of survivals of different groups, proper accounting for censoring and truncation, model variable selection, and residual analysis. Because explaining survival analysis requires more advanced mathematics than many other statistical topics, this book is organized with basic concepts and most frequently used procedures covered in earlier chapters, with more advanced topics near the end and in the appendices. A background in basic linear regression and categorical data analysis, as well as a basic knowledge of calculus and the R system, will help the reader to fully appreciate the information presented. Examples are simple and straightforward while still illustrating key points, shedding light on the application of survival analysis in a way that is useful for graduate students, researchers, and practitioners in biostatistics.

Survival Analysis in Medicine and Genetics - Jialiang Li 2013-06-04

Using real data sets throughout, Survival Analysis in Medicine and Genetics introduces the latest methods for analyzing high-dimensional survival data. It provides thorough coverage of recent statistical developments in the medical and genetics fields. The text mainly addresses special concerns of the survival model. After covering the fundamentals, it discusses interval censoring, nonparametric and semiparametric hazard regression, multivariate survival data analysis, the sub-distribution method for competing risks data, the cure rate model, and Bayesian inference methods. The authors then focus on time-dependent diagnostic medicine and high-dimensional genetic data analysis. Many of the methods are illustrated with clinical examples. Emphasizing the applications of survival analysis techniques in genetics, this book presents a statistical framework for burgeoning research in this area and offers a set of established approaches for statistical analysis. It reveals a new way of looking at how predictors are associated with censored survival time and extracts novel statistical genetic methods for censored survival time outcome from the vast amount of research results in genomics.

Modelling Survival Data in Medical Research - David Collett 1993

Data collected on the time to an event-such as the death of a patient in a medical study-is known as survival data. The methods for analyzing survival data can also be used to analyze data on the time to events such as the recurrence of a disease or relief from symptoms.

Modelling Survival Data in Medical Research begins with an introduction to survival analysis and a description of four studies in which survival data was obtained. These and other data sets are then used to illustrate the techniques presented in the following chapters, including the Cox and Weibull proportional hazards models; accelerated failure time models; models with time-dependent variables; interval-censored survival data; model checking; and use of statistical packages. Designed for statisticians in the pharmaceutical industry and medical research institutes, and for numerate scientists and clinicians analyzing their own data sets, this book also meets the need for an intermediate text which emphasizes the application of the methodology to survival data arising from medical studies.

Sharing Clinical Trial Data - Institute of Medicine 2015-04-20

Data sharing can accelerate new discoveries by avoiding duplicative trials, stimulating new ideas for research, and enabling the maximal scientific knowledge and benefits to be gained from the efforts of clinical trial participants and investigators. At the same time, sharing clinical trial data presents risks, burdens, and challenges. These include the need to protect the privacy and honor the consent of clinical trial participants; safeguard the legitimate economic interests of sponsors; and guard against invalid secondary analyses, which could undermine trust in clinical trials or otherwise harm public health. Sharing Clinical Trial Data presents activities and strategies for the responsible sharing of clinical trial data. With the goal of increasing scientific knowledge to lead to better therapies for patients, this book identifies guiding principles and makes recommendations to maximize the benefits and minimize risks. This report offers guidance on the types of clinical trial data available at different points in the process, the points in the process at which each type of data should be shared, methods for sharing data, what groups should have access to data, and future knowledge and infrastructure needs. Responsible sharing of clinical trial data will allow other investigators to replicate published findings and carry out additional analyses, strengthen the evidence base for regulatory and clinical decisions, and increase the scientific knowledge gained from investments by the funders of clinical trials. The recommendations of Sharing Clinical Trial Data will be useful both now and well into the future as improved sharing of data leads to a stronger evidence base for treatment. This book will be of interest to stakeholders across the spectrum of research--from funders, to researchers, to journals, to physicians, and ultimately, to patients.

Modern Clinical Trial Analysis - Wan Tang 2012-09-05

This volume covers classic as well as cutting-edge topics on the analysis of clinical trial data in biomedical and psychosocial research and discusses each topic in an expository and user-friendly fashion. The intent of the book is to provide an overview of the primary statistical and data analytic issues associated with each of the selected topics, followed by a discussion of approaches for tackling such issues and available software packages for carrying out analyses. While classic topics such as survival data analysis, analysis of diagnostic test data and assessment of measurement reliability are well known and covered in depth by available topic-specific texts, this volume serves a different purpose: it provides a quick introduction to each topic for self-learning, particularly for those who have not done any formal coursework on a given topic but must learn it due to its relevance to their multidisciplinary research. In addition, the chapters on these classic topics will reflect issues particularly relevant to modern clinical trials such as longitudinal designs and new methods for analyzing data from such study designs. The coverage of these topics provides a quick introduction to

these important statistical issues and methods for addressing them. As with the classic topics, this part of the volume on modern topics will enable researchers to grasp the statistical methods for addressing these emerging issues underlying modern clinical trials and to apply them to their research studies.
Handbook of Survival Analysis - John P. Klein 2016-04-19
Handbook of Survival Analysis presents modern techniques and research problems in lifetime data analysis. This area of statistics deals with time-to-event data that is complicated by censoring and the dynamic nature of events occurring in time. With chapters written by leading researchers in the field, the handbook focuses on advances in survival analysis techniques, covering classical and Bayesian approaches. It gives a complete overview of the current status of survival analysis and should inspire further research in the field. Accessible to a wide range of readers, the book provides: An introduction to various areas in survival analysis for graduate students and novices A reference to modern investigations into survival analysis for more established researchers A text or supplement for a second or advanced course in survival analysis A useful guide to statistical methods for analyzing survival data experiments for practicing statisticians
Modelling Survival Data in Medical Research - David Collett 2015-05-04
Modelling Survival Data in Medical Research describes the modelling approach to the analysis of survival data using a wide range of examples from biomedical research.Well known for its nontechnical style, this third edition contains new chapters on frailty models and their applications, competing risks, non-proportional hazards, and dependent censo
Bayesian Causal Survival Analysis in Clinical Trials with Noncompliance - Fang Li 1999

Statistical Methods for Survival Trial Design - Jianrong Wu 2018-06-14
Statistical Methods for Survival Trial Design: With Applications to Cancer Clinical Trials Using R provides a thorough presentation of the principles of designing and monitoring cancer clinical trials in which time-to-event is the primary endpoint. Traditional cancer trial designs with time-to-event endpoints are often limited to the exponential model or proportional hazards model. In practice, however, those model assumptions may not be satisfied for long-term survival trials. This book is the first to cover comprehensively the many newly developed methodologies for survival trial design, including trial design under the Weibull survival models; extensions of the sample size calculations under the proportional hazard models; and trial design under mixture cure models, complex survival models, Cox regression models, and competing-risk models. A general sequential procedure based on the sequential conditional probability ratio test is also implemented for survival trial monitoring. All methodologies are presented with sufficient detail for interested researchers or graduate students.
Survival Models and Data Analysis - Regina C. Elandt-Johnson 1980-09-17
Survival analysis deals with the distribution of life times, essentially the times from an initiating event such as birth or the start of a job to some terminal event such as death or pension. This book, originally published in 1980, surveys and analyzes methods that use survival measurements and concepts, and helps readers apply the appropriate method for a given situation. Four broad sections cover introductions to data, univariate survival function, multiple-failure data, and advanced topics.
Survival Analysis of Complex Featured Data with Measurement Error - Li-Pang Chen 2019
Survival analysis plays an important role in many fields, such as cancer research, clinical trials, epidemiological studies, actuarial science, and so on. A large body of methods on analyzing survival data have been developed. However, many

important problems have still not been fully explored. In this thesis, we focus on the analysis of survival data with complex features. In Chapter 1, we review relevant topics including survival analysis, the measurement error model, the graphical model, and variable selection. Graphical models are useful in characterizing the dependence structure of variables. They have been commonly used for analysis of high-dimensional data, including genetic data and data with network structures. Many estimation procedures have been developed under various graphical models with a stringent assumption that the associated variables must be measured precisely. In applications, this assumption, however, is often unrealistic and mismeasurement in variables is usually presented in data. In Chapter 2, we investigate the high-dimensional graphical model with error-prone variables. We propose valid estimation procedures to account for measurement error effects. Theoretical results are established for the proposed methods and numerical studies are reported to assess the performance of our proposed methods. In Chapter 3, we consider survival analysis with network structures and measurement error in covariates. In survival data analysis, the Cox proportional hazards (PH) model is perhaps the most widely used model to feature the dependence of survival times on covariates. While many inference methods have been developed under such a model or its variants, those models are not adequate for handling data with complex structured covariates. High-dimensional survival data often entail several features: (1) many covariates are inactive in explaining the survival information, (2) active covariates are associated in a network structure, and (3) some covariates are error-contaminated. To hand such kinds of survival data, we propose graphical proportional hazards measurement error models, and develop inferential procedures for the parameters of interest. Our proposed models significantly enlarge the scope of the usual Cox PH model and have great flexibility in characterizing survival data. Theoretical results are established to justify the proposed methods. Numerical studies are conducted to assess the performance of the proposed methods. In Chapter 4, we focus on sufficient dimension reduction for high-dimensional survival data with covariate measurement error. Sufficient dimension reduction (SDR) is an important tool in regression analysis which reduces the dimension of covariates without losing predictive information. Several methods have been proposed to handle data with either censoring in the response or measurement error in covariates. However, little research is available to deal with data having these two features simultaneously. Moreover, the analysis becomes more challenging when data contain ultrahigh-dimensional covariates. In Chapter 4, we examine this problem. We start with considering the cumulative distribution function in regular settings and propose a valid SDR method to incorporate the effects of both censored data and covariates measurement error. Next, we extend the proposed method to handle ultrahigh-dimensional data. Theoretical results of the proposed methods are established. Numerical studies are reported to assess the performance of the proposed methods. In Chapter 5, we slightly switch our attention to examine sampling issues concerning survival data. Specifically, we discuss survival analysis for left-truncated and right-censored data with covariate measurement error. Many methods have been developed for analyzing survival data which commonly involve right-censoring. These methods, however, are challenged by complex features pertinent to the data collection as well as the nature of data themselves. Typically, biased samples caused by left-truncation or length-biased sampling and measurement error are often accompanying with survival analysis. While such data frequently arise in practice, little work has been available in the literature. In Chapter 5, we study this important

problem and explore valid inference methods for handling left-truncated and right-censored survival data with measurement error under the widely used Cox model. We exploit a flexible estimator for the survival model parameters which does not require specification of the baseline hazard function. To improve the efficiency, we further develop an augmented non-parametric maximum likelihood estimator. We establish asymptotic results for the proposed estimators and examine the efficiency and robustness issues of the proposed estimators. The proposed methods enjoy appealing features that the distributions of the covariates and of the truncation times are left unspecified. Numerical studies are reported to assess the performance of the proposed methods. In Chapter 6, we study outstanding issues on model selection and model averaging for survival data with measurement error. Model selection plays a critical role in statistical inference and a vast literature has been devoted to this topic. Despite extensive research attention on model selection, research gaps still remain. An important but unexplored problem concerns model selection for truncated and censored data with measurement error. Although analysis of left-truncated and right-censored (LTRC) data has received extensive interests in survival analysis, there has been no research on model selection for LTRC data, let alone LTRC data involving with measurement error. In Chapter 6, we take up this important problem and develop inferential procedures to handle model selection for LTRC data with measurement error in covariates. Our development employs the local model misspecification framework and emphasizes the use of the focus information criterion (FIC). We develop valid estimators using the model averaging scheme and establish theoretical results to justify the validity of our methods. Numerical studies are conducted to assess the performance of the proposed methods. Finally, Chapter 7 summarizes the thesis with discussions.

Nonparametric Analysis of Survival Data in Staggered-entry Clinical Trials - Minggao Gu 1987

Survival Analysis with Complex Censoring Mechanisms with Applications in Population-based Studies and Clinical Trials - Megan Kay Diane Othus 2009

Population-based studies and clinical trials provide many interesting methodological problems that render important policy implications as well as better explainations of disease progression processes. This thesis is to answer three such questions. Trends in United States cancer survival motivated a statistical method for survival data that may be subject to dependent censoring in disease populations that may contain a portion of long-term cancer surviors. Prostate cancer trends motivated work on a survival model for populations that may have long-term survivors and that exhibit a change-point effect in important covariates or predictors. Finally, a clinical trial on childhood acute lymphoblastic leukemia motivated work on a survival model for clustered data that explicitly models the correlation of failure times but also allows for population-level interpretation of survival parameters.

Clinical Statistics: Introducing Clinical Trials, Survival Analysis, and Longitudinal Data Analysis - Olga Korosteleva 2009

Clinical Statistics: Introducing Clinical Trials, Survival Analysis, and Longitudinal Data Analysis provides the mathematic background necessary for students preparing for a career as a statistician in the biomedical field. The manual explains the steps a clinical statistician must take in clinical trials from protocol writing to subject randomization, to data monitoring, and on to writing a final report to the FDA. All of the necessary fundamentals of statistical analysis: survival and longitudinal data analysis are included. SAS procedures are explained with simple examples and the mathematics behind these SAS procedures are covered in detail with the statistical software program SAS

which is implemented throughout the text. Complete codes are given for every example found in the text. The exercises featured throughout the guide are both theoretical and applied making it appropriate for those moving on to different clinical settings. Students will find Clinical Statistics to be a handy lab reference for coursework and in their future careers.

Methods for the Analysis of Censored Survival Time Data in Clinical Trials - Stephan Ogenstad 1982

Small Clinical Trials - Institute of Medicine 2001-01-01

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 predesigned specifications as opposed to incremental improvement.

Modelling Survival Data in Medical Research, Third Edition - David Collett 2014-12-11

Modelling Survival Data in Medical Research describes the modelling approach to the analysis of survival data using a wide range of examples from biomedical research. Well known for its nontechnical style, this third edition contains new chapters on frailty models and their applications, competing risks, non-proportional hazards, and dependent censoring. It also describes techniques for modelling the occurrence of multiple events and event history analysis. Earlier chapters are now expanded to include new material on a number of topics, including measures of predictive ability and flexible parametric models. Many new data sets and examples are included to illustrate how these techniques are used in modelling survival data. Bibliographic notes and suggestions for further reading are provided at the end of each chapter. Additional data sets to obtain a fuller appreciation of the methodology, or to be used as student exercises, are provided in the appendix. All data sets used in this book are also available in electronic format online. This book is an invaluable resource for statisticians in the pharmaceutical industry, professionals in medical research institutes, scientists and clinicians who are analyzing their own data, and students taking undergraduate or postgraduate courses in survival analysis.

Clinical Trial Data Analysis Using R - Ding-Geng (Din) Chen 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.

Bayesian Survival Analysis - Joseph G. Ibrahim 2013-03-09

Survival analysis arises in many fields of study including medicine, biology, engineering, public health, epidemiology, and economics. This book provides a comprehensive treatment of Bayesian survival analysis. It presents a balance between theory and applications, and for each class of models discussed, detailed examples and analyses from case studies are presented whenever possible. The applications are all from the health sciences, including cancer, AIDS, and the environment.

Analysing Survival Data from Clinical Trials and Observational Studies - Ettore Marubini 2004-07-02

A practical guide to methods of survival analysis for medical researchers with limited statistical experience. Methods and techniques described range from descriptive and exploratory analysis to multivariate regression methods. Uses illustrative data from actual clinical trials and observational studies to describe methods of analysing and reporting results. Also reviews the features and performance of statistical software available for applying the methods of analysis discussed.

Survival Analysis with Interval-Censored Data - Kris Bogaerts 2017-11-20

Survival Analysis with Interval-Censored Data: A Practical Approach with Examples in R, SAS, and BUGS provides the reader with a practical introduction into the analysis of interval-censored survival times. Although many theoretical developments have appeared in the last fifty years, interval censoring is often ignored in practice. Many are unaware of the impact of inappropriately dealing with interval censoring. In addition, the necessary software is at times difficult to trace. This book fills in the gap between theory and practice. Features: -Provides an overview of frequentist as well as Bayesian methods. -Include a focus on practical aspects and applications. -Extensively illustrates the methods with examples using R, SAS, and BUGS. Full programs are available on a supplementary website. The authors: Kris Bogaerts is project manager at I-BioStat, KU Leuven. He received his PhD in science (statistics) at KU Leuven on the analysis of interval-censored data. He has gained expertise in a great variety of statistical topics with a focus on the design and analysis of clinical trials. Arnošt Komárek is associate professor of statistics at Charles University, Prague. His subject area of expertise covers mainly survival analysis with the emphasis on interval-censored data and classification based on longitudinal data. He is past chair of the Statistical Modelling Society and editor of Statistical Modelling: An International Journal. Emmanuel Lesaffre is professor of biostatistics at I-BioStat, KU Leuven. His research interests include Bayesian methods, longitudinal data analysis,

statistical modelling, analysis of dental data, interval-censored data, misclassification issues, and clinical trials. He is the founding chair of the Statistical Modelling Society, past-president of the International Society for Clinical Biostatistics, and fellow of ISI and ASA.

SAS Survival Analysis Techniques for Medical Research - Alan B. Cantor 2003

If you are new to survival analysis or want to expand your capabilities in this area, you'll benefit from Alan Cantor's SAS Survival Analysis Techniques for Medical Research, Second Edition, which presents the theory and methods of survival analysis along with excellent discussions of the SAS procedures used to implement the methods described. New features of the second edition include a discussion of permutation and randomization tests; a discussion of the use of data imputation; an expanded discussion of power for Cox regression; descriptions of the new features of SAS 9, such as confidence bands for the Kaplan-Meier curve; appendixes that cover mathematical and statistical background topics needed in survival analysis; and student exercises. The new features, along with several useful macros and numerous examples, make this a suitable textbook for a course in survival analysis for biostatistics majors and majors in related fields. This book excels at presenting complex ideas in a way that enables those without a strong technical background to understand and apply the concepts and techniques.

Applying Survival Analysis Techniques to Interim Analysis and Sample Size Reassessment of Clinical Trials with a Dichotomous Endpoint - Alison L. Pedley 2011

Abstract: A two-sample Z test of proportions is often performed in randomized clinical trials designed to assess the superiority of an experimental treatment to a control with respect to a long-term dichotomous primary endpoint, such as 1-year mortality. Due to the staggered entry of participants across the trial's recruitment period, only a portion of enrolled participants have complete follow- up data available at the time of an interim analysis. Typically, the interim evaluation of trial hypotheses is performed using the same test statistic as the test statistic planned for the final analysis. However, application of the Z test of proportions at interim analysis results in a potentially substantial reduction to the number of participants that are able to contribute to the analysis. In this dissertation, methodology for the use of the log-rank test, which incorporates data of all enrolled participants regardless of the amount of time each has been followed, in the interim analysis of trials with a dichotomous final primary endpoint is developed and evaluated. Although the overall power and type I error rates of the newly proposed methodology and the standard methodology are comparable under the assumption of proportional hazards and event rates less than 50%, the efficiency of using the log-rank test during the interim analysis was realized in terms of an increased probability of early trial termination for overwhelming efficacy resulting in potential for shorter trials and smaller sized trials. Methodology for using the log-rank test was also developed for and applied to trials incorporating an adaptation for sample size re-estimation at interim based on the conditional power of achieving a significant result by the end of the trial. In the context of sample size re-estimation, the use of the log-rank test not only increased the probability of declaring superiority of the experimental treatment over the control at the time of interim analysis, but increased the overall power. Regardless of whether or not sample size re-estimation is used, greater efficiency is attained when the log-rank test is performed at interim analysis as the differential between the percentages of subjects enrolled and with complete follow-up at interim analysis increases.

Dynamic Prediction in Clinical

Survival Analysis - Hans van Houwelingen 2011-11-09
There is a huge amount of literature on statistical models for the prediction of survival after diagnosis of a wide range of diseases like cancer, cardiovascular disease, and chronic kidney disease. Current practice is to use prediction models based on the Cox proportional hazards model and to present those as static models for remaining lifetime after diagnosis or treatment. In contrast, Dynamic Prediction in Clinical Survival Analysis focuses on dynamic models for the remaining lifetime at later points in time, for instance using landmark models. Designed to be useful to applied statisticians and clinical epidemiologists, each chapter in the book has a practical focus on the issues of working with real life data. Chapters conclude with additional material either on the interpretation of the models, alternative models, or theoretical background. The book consists of four parts: Part I deals with prognostic models for survival data using (clinical) information available at baseline, based on the Cox model Part II is about prognostic models for survival data using (clinical) information available at baseline, when the proportional hazards assumption of the Cox model is violated Part III is dedicated to the use of time-dependent information in dynamic prediction Part IV explores dynamic prediction models for survival data using genomic data Dynamic Prediction in Clinical Survival Analysis summarizes cutting-edge research on the dynamic use of predictive models with traditional and new approaches. Aimed at applied statisticians who actively analyze clinical data in collaboration with clinicians, the analyses of the different data sets throughout the book demonstrate how predictive models can be obtained from proper data sets.

Analysis of Clinical Trials Using SAS - Alex Dmitrienko 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.

Recent Advances in Clinical Trial Design and Analysis - Peter F. Thall 2012-12-06
Clinical trials have two purposes -- to treat the patients in the trial, and to obtain information which increases our understanding of the disease and especially how patients

respond to treatment. Statistical design provides a means to achieve both these aims, while statistical data analysis provides methods for extracting useful information from the trial data. Recent advances in statistical computing have enabled statisticians to implement very rapidly a broad array of methods which previously were either impractical or impossible. Biostatisticians are now able to provide much greater support to medical researchers working in both clinical and laboratory settings. As our collective toolkit of techniques for analyzing data has grown, it has become increasingly difficult for biostatisticians to keep up with all the developments in our own field. Recent Advances in Clinical Trial Design and Analysis brings together biostatisticians doing cutting-edge research and explains some of the more recent developments in biostatistics to clinicians and scientists who work in clinical trials.

Sequential Experimentation in Clinical Trials - Jay Bartroff 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.

Statistical Aspects of the Design and Analysis of Clinical Trials - Brian S Everitt 2004-02-26

Fully updated, this revised edition describes the statistical aspects of both the design and analysis of trials, with particular emphasis on the more recent methods of analysis. About 8000 clinical trials are undertaken annually in all areas of medicine, from the treatment of acne to the prevention of cancer. Correct interpretation of the data from such trials depends largely on adequate design and on performing the appropriate statistical analyses. This book provides a useful guide to medical statisticians and others faced with the often difficult problems of designing and analysing clinical trials. Contents:An Introduction to Clinical TrialsTreatment Allocation, the Size of Trials and Reporting ResultsMonitoring Trial Progress: Outcome Measures, Compliance, Dropouts and Interim AnalysesBasic Analyses of Clinical Trials, the Generalised Linear Model and the Economic Evaluation of TrialsSimple Approaches to the Analysis of Longitudinal Data from Clinical TrialsMultivariate Normal Regression Models for Longitudinal Data from Clinical TrialsModels for Non-Normal Longitudinal Data from Clinical TrialsSurvival AnalysisBayesian

Methods Longitudinal DataMeta-Analysis Readership: Applied statisticians in medicine, researchers dealing with clinical trials and pharmaceutical companies. Keywords:Clinical Trials;Longitudinal Data;Random Effects Models;Dropouts;Survival Analysis, Bayesian MethodsReviews:“… given a keen amateur interest and an ability to skip the occasional rather daunting-looking equation this book is surprisingly accessible … There's an introductory chapter containing an excellent historical overview.”Transactions of Royal Society of Tropical Medicine and Hygiene “In providing a concise description of the statistical aspects of the design and analysis of clinical trials, free of any major typographical errors, the authors have succeeded. Those concerned with the correct design and analysis of clinical trials, but wishing to avoid either the advanced theoretical aspects or too much focus on application of methodologies, will find this book to be very accessible with relatively up-to-date references.”Pharmaceutical Statistics

Statistical Methods for Survival Data Analysis - Elisa T. Lee 1992-05-07
Intended to meet the requirements for a single volume which covers methodologies appropriate for the analysis of survival data. Along with guidelines for the planning and design of clinical trials this expanded Second Edition offers a thorough discussion of population lifetables, real life examples, numerous exercises, computer programs for survival data analysis plus an updated reference list which includes a large number of recently published papers.

Survival Analysis for Economic Evaluations Alongside Clinical Trials :: Extrapolation with Patient-level Data - Nicholas Latimer

Randomized Phase II Cancer Clinical Trials - Sin-Ho Jung 2013-05-02
In cancer research, a traditional phase II trial is designed as a single-arm trial that compares the experimental therapy to a historical control. This simple trial design has led to several adverse issues, including increased false positivity of phase II trial results and negative phase III trials. To rectify these problems, oncologists and biostatisticians have begun to use a randomized phase II trial that compares an experimental therapy with a prospective control therapy. Randomized Phase II Cancer Clinical Trials explains how to properly select and accurately use diverse statistical methods for designing and analyzing phase II trials. The author first reviews the statistical methods for single-arm phase II trials since some methodologies for randomized phase II trials stem from single-arm phase II trials and many phase II cancer clinical trials still use single-arm designs. The book then presents methods for randomized phase II trials and describes statistical methods for both single-arm and randomized phase II trials. Although the text focuses on phase II cancer clinical trials, the statistical methods covered can also be used (with minor modifications) in phase II trials for other diseases and in phase III cancer clinical trials. Suitable for cancer clinicians and biostatisticians, this book shows how randomized phase II trials with a prospective control resolve the shortcomings of traditional single-arm phase II trials. It provides readers with numerous statistical design and analysis methods for randomized phase II trials in oncology.