Analysis Of Clinical Trials Using Sas A Practical Guide

#clinical trials analysis #SAS programming #biostatistics clinical research #statistical analysis healthcare #drug development SAS

This practical guide offers comprehensive insights into the meticulous analysis of clinical trials using SAS, empowering researchers and statisticians with essential programming techniques. It covers critical biostatistics methods and best practices for handling complex clinical data, serving as an invaluable resource for rigorous and compliant research in pharmaceutical and medical fields.

Analysis of Clinical Trials Using SAS

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.

Pharmaceutical Statistics Using SAS

Introduces a range of data analysis problems encountered in drug development and illustrates them using case studies from actual pre-clinical experiments and clinical studies. Includes a discussion of methodological issues, practical advice from subject matter experts, and review of relevant regulatory guidelines.

Pharmaceutical Statistics Using SAS

Offering extensive coverage of cutting-edge biostatistical methodology used in drug development, this essential reference explores the practical problems facing today's drug developers. It is written by well-known experts in the pharmaceutical industry and provides relevant tutorial material and SAS examples.

Pharmaceutical Statistics Using SAS

Pharmaceutical Statistics Using SAS: A Practical Guide offers extensive coverage of cutting-edge biostatistical methodology used in drug development and the practical problems facing today's drug developers. Written by well-known experts in the pharmaceutical industry Alex Dmitrienko, Christy Chuang-Stein, and Ralph D'Agostino, it provides relevant tutorial material and SAS examples to help readers new to a certain area of drug development quickly understand and learn popular data analysis methods and apply them to real-life problems. Step-by-step, the book introduces a wide range of data analysis problems encountered in drug development and illustrates them using a wealth of case studies from actual pre-clinical experiments and clinical studies. The book also provides SAS code for solving the problems. Among the topics addressed are these: drug discovery experiments to identify promising chemical compounds animal studies to assess the toxicological profile of these compounds clinical pharmacology studies to examine the properties of new drugs in healthy human subjects Phase II and Phase III clinical trials to establish therapeutic benefits of experimental drugs. Additional features include a discussion of methodological issues, practical advice from subject-matter experts, and review of relevant regulatory guidelines. Most chapters are self-contained and include a fair amount of high-level introductory material to make them accessible to a broad audience of pharmaceutical scientists. This book will also serve as a useful reference for regulatory scientists as well as academic researchers and graduate students.

Analyzing Longitudinal Clinical Trial Data

Analyzing Longitudinal Clinical Trial Data: A Practical Guide provide practical and easy to implement approaches for bringing the latest theory on analysis of longitudinal clinical trial data into routine practice.?This book, with its example-oriented approach that includes numerous SAS and R code fragments, is an essential resource for statisticians and graduate students specializing in medical research. The authors provide clear descriptions of the relevant statistical theory and illustrate practical considerations for modeling longitudinal data. Topics covered include choice of endpoint and statistical test; modeling means and the correlations between repeated measurements; accounting for covariates; modeling categorical data; model verification; methods for incomplete (missing) data that includes the latest developments in sensitivity analyses, along with approaches for and issues in choosing estimands; and means for preventing missing data. Each chapter stands alone in its coverage of a topic. The concluding chapters provide detailed advice on how to integrate these independent topics into an over-arching study development process and statistical analysis plan.

Pharmaceutical Statistics Using SAS

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Clinical Trials

This book explains statistics specifically for a medically literate audience. Readers gain not only an understanding of the basics of medical statistics, but also a critical insight into how to review and evaluate clinical trial evidence.

Modern Approaches to Clinical Trials Using SAS

Get the tools you need to use SAS® in clinical trial design! Unique and multifaceted, Modern Approaches to Clinical Trials Using SAS: Classical, Adaptive, and Bayesian Methods, edited by Sandeep M. Menon and Richard C. Zink, thoroughly covers several domains of modern clinical trial design: classical, group sequential, adaptive, and Bayesian methods that are applicable to and widely used in various phases of pharmaceutical development. Written for biostatisticians, pharmacometricians, clinical developers, and statistical programmers involved in the design, analysis, and interpretation of clinical trials, as well as students in graduate and postgraduate programs in statistics or biostatistics, the book touches on a wide variety of topics, including dose-response and dose-escalation designs; sequential methods to stop trials early for overwhelming efficacy, safety, or futility; Bayesian designs that incorporate historical data; adaptive sample size re-estimation; adaptive randomization to allocate subjects to more effective treatments; and population enrichment designs. Methods are illustrated using clinical trials from diverse therapeutic areas, including dermatology, endocrinology, infectious disease, neurology, oncology, and rheumatology. Individual chapters are authored by renowned contributors, experts, and key opinion leaders from the pharmaceutical/medical device industry or academia. Numerous real-world examples and sample SAS code enable users to readily apply novel clinical trial design and analysis methodologies in practice.

Common Statistical Methods for Clinical Research with SAS Examples

Thoroughly updated edition of the popular introductory statistics book for clinical researchers. This new edition has been extensively updated to include the use of ODS graphics in numerous examples as well as a new emphasis on PROC MIXED.

Missing Data in Clinical Studies

Missing Data in Clinical Studies provides a comprehensive account of the problems arising when data from clinical and related studies are incomplete, and presents the reader with approaches to effectively address them. The text provides a critique of conventional and simple methods before moving on to discuss more advanced approaches. The authors focus on practical and modeling concepts, providing an extensive set of case studies to illustrate the problems described. Provides a practical guide to the analysis of clinical trials and related studies with missing data. Examines the problems caused by missing data, enabling a complete understanding of how to overcome them. Presents conventional, simple methods to tackle these problems, before addressing more advanced approaches, including sensitivity analysis, and the MAR missingness mechanism. Illustrated throughout with real-life case studies and worked examples from clinical trials. Details the use and implementation of the necessary statistical software, primarily SAS. Missing Data in Clinical Studies has been developed through a series of courses and lectures. Its practical approach will appeal to applied statisticians and biomedical researchers, in particular those in the biopharmaceutical industry, medical and public health organisations. Graduate students of biostatistics will also find much of benefit.

SAS Graphics for Clinical Trials by Example

Create industry-compliant graphs with this practical guide for professionals Analysis of clinical trial results is easier when the data is presented in a visual form. However, clinical graphs must conform to specific guidelines in order to satisfy regulatory agency requirements. If you are a programmer working in the health care and life sciences industry and you want to create straightforward, visually appealing graphs using SAS, then this book is designed specifically for you. Written by two experienced practitioners, the book explains why certain graphs are requested, gives the necessary code to create the graphs, and shows you how to create graphs from ADaM data sets modeled on real-world CDISC pilot study data. SAS Graphics for Clinical Trials by Example demonstrates step-by-step how to create both simple and complex graphs using Graph Template Language (GTL) and statistical graphics procedures, including the SGPLOT and SGPANEL procedures. You will learn how to generate commonly used plots such as Kaplan-Meier plots and multi-cell survival plots as well as special purpose graphs such as Venn diagrams and interactive graphs. Because your graph is only as good as the aesthetic appearance of the output, you will learn how to create a custom style, change attributes, and set output options. Whether you are just learning how to produce graphs or have been working with graphs for a while, this book is a must-have resource to solve even the most challenging clinical graph problems.

Clinical Trial Data Analysis Using R and SAS

Review of the First Edition "The goal of this book, as stated by the authors, is to fill the knowledge gap that exists between developed statistical methods and the applications of these methods. Overall, this book achieves the goal successfully and does a nice job. I would highly recommend it ...The example-based approach is easy to follow and makes the book a very helpful desktop reference for many biostatistics methods."—Journal of Statistical Software Clinical Trial Data Analysis Using R and SAS, Second Edition provides a thorough presentation of biostatistical analyses of clinical trial data with step-by-step implementations using R and SAS. The book’s practical, detailed approach draws on the authors’ 30 years’ experience in biostatistical research and clinical development. The authors develop step-by-step analysis code using appropriate R packages and functions and SAS PROCS, which enables readers to gain an understanding of the analysis methods and R and SAS implementation so that they can use these two popular software packages to analyze their own clinical trial data. What’s New in the Second Edition Adds SAS programs along with the R programs for clinical trial data analysis. Updates all the statistical analysis with updated R packages. Includes correlated data analysis with multivariate analysis of variance. Applies R and SAS to clinical trial data from hypertension, duodenal ulcer, beta blockers, familial andenomatous polyposis, and breast cancer trials. Covers the biostatistical aspects of various clinical trials, including treatment comparisons, time-to-event endpoints, longitudinal clinical trials, and bioequivalence trials.

Estimands, Estimators and Sensitivity Analysis in Clinical Trials

The concepts of estimands, analyses (estimators), and sensitivity are interrelated. Therefore, great need exists for an integrated approach to these topics. This book acts as a practical guide to developing and implementing statistical analysis plans by explaining fundamental concepts using accessible language, providing technical details, real-world examples, and SAS and R code to implement analyses. The updated ICH guideline raises new analytic and cross-functional challenges for statisticians. Gaps between different communities have come to surface, such as between causal inference and clinical trialists, as well as among clinicians, statisticians, and regulators when it comes to communicating decision-making objectives, assumptions, and interpretations of evidence. This book lays out a path toward bridging some of these gaps. It offers ·A common language and unifying framework along with the technical details and practical guidance to help statisticians meet the challenges ·A thorough treatment of intercurrent events (ICEs), i.e., postrandomization events that confound interpretation of outcomes and five strategies for ICEs in ICH E9 (R1) ·Details on how estimands, integrated into a principled study development process, lay a foundation for coherent specification of trial design, conduct, and analysis needed to overcome the issues caused by ICEs: ·A perspective on the role of the intention-to-treat principle ·Examples and case studies from various areas ·Example code in SAS and R ·A connection with causal inference ·Implications and methods for analysis of longitudinal trials with missing data Together, the authors have offered the readers their ample expertise in clinical trial design and analysis, from an industrial and academic perspective.

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Clinical Trials with Missing Data

This book provides practical guidance for statisticians, clinicians, and researchers involved in clinical trials in the biopharmaceutical industry, medical and public health organisations. Academics and students needing an introduction to handling missing data will also find this book invaluable. The authors describe how missing data can affect the outcome and credibility of a clinical trial, show by examples how a clinical team can work to prevent missing data, and present the reader with approaches to address missing data effectively. The book is illustrated throughout with realistic case studies and worked examples, and presents clear and concise guidelines to enable good planning for missing data. The authors show how to handle missing data in a way that is transparent and easy to understand for clinicians, regulators and patients. New developments are presented to improve the choice and implementation of primary and sensitivity analyses for missing data. Many SAS code examples are included – the reader is given a toolbox for implementing analyses under a variety of assumptions.

Validating Clinical Trial Data Reporting with SAS

This indispensable guide focuses on validating programs written to support the clinical trial process from after the data collection stage to generating reports and submitting data and output to the Food and Drug Administration.

Common Statistical Methods for Clinical Research with SAS Examples

This updated edition provides clinical researchers with an invaluable aid for understanding the statistical methods cited most frequently in clinical protocols, statistical analysis plans, clinical and statistical reports, and medical journals. The text is written in a way that takes the non-statistician through each test using examples, yet substantive details are presented that benefit even the most experienced data analysts.

Introduction to Statistical Methods for Clinical Trials

Clinical trials have become essential research tools for evaluating the benefits and risks of new interventions for the treatment and prevention of diseases, from cardiovascular disease to cancer to AIDS. Based on the authors' collective experiences in this field, Introduction to Statistical Methods for Clinical Trials presents various statistical topics relevant to the design, monitoring, and analysis of a clinical trial. After reviewing the history, ethics, protocol, and regulatory issues of clinical trials, the book provides guidelines for formulating primary and secondary questions and translating clinical questions into statistical ones. It examines designs used in clinical trials, presents methods for determining sample size, and introduces constrained randomization procedures. The authors also discuss how various types of data must be collected to answer key questions in a trial. In addition, they explore common analysis methods, describe statistical methods that determine what an emerging trend represents, and

present issues that arise in the analysis of data. The book concludes with suggestions for reporting trial results that are consistent with universal guidelines recommended by medical journals. Developed from a course taught at the University of Wisconsin for the past 25 years, this textbook provides a solid understanding of the statistical approaches used in the design, conduct, and analysis of clinical trials.

Comparing Clinical Measurement Methods

This book provides a practical guide to analysis of simple and complex method comparison data, using Stata, SAS and R. It takes the classical Limits of Agreement as a starting point, and presents it in a proper statistical framework. The model serves as a reference for reporting sources of variation and for providing conversion equations and plots between methods for practical use, including prediction uncertainty. Presents a modeling framework for analysis of data and reporting of results from comparing measurements from different clinical centers and/or different methods. Provides the practical tools for analyzing method comparison studies along with guidance on what to report and how to plan comparison studies and advice on appropriate software. Illustrated throughout with computer examples in R. Supported by a supplementary website hosting an R-package that performs the major part of the analyses needed in the area. Examples in SAS and Stata for the most common situations are also provided. Written by an acknowledged expert on the subject, with a long standing experience as a biostatistician in a clinical environment and a track record of delivering training on the subject. Biostatisticians, clinicians, medical researchers and practitioners involved in research and analysis of measurement methods and laboratory investigations will benefit from this book. Students of statistics, biostatistics, and the chemical sciences will also find this book useful.

A Practical Approach to Quantitative Validation of Patient-Reported Outcomes

In A Practical Approach to Quantitative Validation of Patient-Reported Outcomes, two distinguished researchers, with 50 years of collective research experience and hundreds of publications on patient-centered research, deliver a detailed and comprehensive exposition on the critical steps required for quantitative validation of patient-reported outcomes (PROs). The book provides an incisive and instructional explanation and discussion on major aspects of psychometric validation methodology on PROs, especially relevant for medical applications sponsored by the pharmaceutical industry, where SAS is the primary software, and evaluated in regulatory and other healthcare environments. Central topics include test-retest reliability, exploratory and confirmatory factor analyses, construct and criterion validity, responsiveness and sensitivity, interpretation of PRO scores and findings, and meaningful within-patient change and clinical important difference. The authors provide step-by-step guidance while walking readers through how to structure data prior to a PRO analysis and demonstrate how to implement analyses with simulated examples grounded in real-life scenarios. Readers will also find: A thorough introduction to patient-reported outcomes, including their definition, development, and psychometric validation Comprehensive explorations of the validation workflow, including discussions of clinical trials as a data source for validation and the validation workflow for single- and multi-item scales In-depth discussions of key concepts related to a validation of a measurement scale. Special attention is given to the US Food and Drug Administration (FDA) guidance on development and validation of the PROs, which lay the foundation and inspiration for the analytic methods executed. A Practical Approach to Quantitative Validation of Patient-Reported Outcomes is a required reference that will benefit psychometricians, statisticians, biostatisticians, epidemiologists, health service and public health researchers, outcome research scientists, regulators, and payers.

Study Design and Statistical Analysis

This book takes the reader through the entire research process: choosing a question, designing a study, collecting the data, using univariate, bivariate and multivariable analysis, and publishing the results. It does so by using plain language rather than complex derivations and mathematical formulae. It focuses on the nuts and bolts of performing research by asking and answering the most basic questions about doing research studies. Making good use of numerous tables, graphs and tips, this book helps to demystify the process. A generous number of up-to-date examples from the clinical literature give an illustrated and practical account of how to use multivariable analysis.

Risk-Based Monitoring and Fraud Detection in Clinical Trials Using JMP and SAS

International guidelines recommend that clinical trial data should be actively reviewed or monitored; the well-being of trial participants and the validity and integrity of the final analysis results are at

stake. Risk-based monitoring (RBM) makes use of central computerized review of clinical trial data and site metrics to determine if and when clinical sites should receive more extensive quality review or intervention. Risk-Based Monitoring and Fraud Detection in Clinical Trials Using JMP and SAS describes analyses for RBM that incorporate and extend the recommendations of TransCelerate Biopharm Inc., methods to detect potential patient-or investigator misconduct, snapshot comparisons to more easily identify new or modified data, and other novel visual and analytical techniques to enhance safety and quality reviews. The analytical methods described enable the clinical trial team to take a proactive approach to data quality and safety to streamline clinical development activities and address shortcomings while the study is ongoing.

Cross-over Trials in Clinical Research

Cross-over trials are an important class of design used in the pharmaceutical industry and medical research, and their use continues to grow. Cross-over Trials in Clinical Research, Second Edition has been fully updated to include the latest methodology used in the design and analysis of cross-over trials. It includes more background material, greater coverage of important statistical techniques, including Bayesian methods, and discussion of analysis using a number of statistical software packages. * Comprehensive coverage of the design and analysis of cross-over trials. * Each technique is carefully explained and the mathematics is kept to a minimum. * Features many real and original examples, taken from the author's vast experience. * Includes discussion of analysis using SAS, S-Plus and, GenStat, StatXact and Excel. * Written in a style suitable for statisticians and physicians alike. * Computer programs to accompany the examples in the book can be downloaded from the Web Primarily aimed at statisticians and researchers working in the pharmaceutical industry, the book will also appeal to physicians involved in clinical research and students of medical statistics.

Clinical Data Quality Checks for CDISC Compliance Using SAS

Clinical Data Quality Checks for CDISC Compliance using SAS is the first book focused on identifying and correcting data quality and CDISC compliance issues with real-world innovative SAS programming techniques such as Proc SQL, metadata and macro programming. Learn to master Proc SQL’s subqueries and summary functions for multi-tasking process. Drawing on his more than 25 years’ experience in the pharmaceutical industry, the author provides a unique approach that empowers SAS programmers to take control of data quality and CDISC compliance. This book helps you create a system of SDTM and ADaM checks that can be tracked for continuous improvement. How often have you encountered issues such as missing required variables, duplicate records, invalid derived variables and invalid sequence of two dates? With the SAS programming techniques introduced in this book, you can start to monitor these and more complex data and CDISC compliance issues. With increased standardization in SDTM and ADaM specifications and data values, codelist dictionaries can be created for better organization, planning and maintenance. This book includes a SAS program to create excel files containing unique values from all SDTM and ADaM variables as columns. In addition, another SAS program compares SDTM and ADaM codelist dictionaries with codelists from define.xml specifications. Having tools to automate this process greatly saves time from doing it manually. Features SDTMs and ADaMs Vitals SDTMs and ADaMs Data CDISC Specifications Compliance CDISC Data Compliance Protocol Compliance Codelist Dictionary Compliance

A Handbook of Statistical Graphics Using SAS ODS

Easily Use SAS to Produce Your Graphics Diagrams, plots, and other types of graphics are indispensable components in nearly all phases of statistical analysis, from the initial assessment of the data to the selection of appropriate statistical models to the diagnosis of the chosen models once they have been fitted to the data. Harnessing the full graphics capabilities of SAS, A Handbook of Statistical Graphics Using SAS ODS covers essential graphical methods needed in every statistician’s toolkit. It explains how to implement the methods using SAS 9.4. The handbook shows how to use SAS to create many types of statistical graphics for exploring data and diagnosing fitted models. It uses SAS’s newer ODS graphics throughout as this system offers a number of advantages, including ease of use, high quality of results, consistent appearance, and convenient semiautomatic graphs from the statistical procedures. Each chapter deals graphically with several sets of example data from a wide variety of areas, such as epidemiology, medicine, and psychology. These examples illustrate the use of graphic displays to give an overview of data, to suggest possible hypotheses for testing new data, and to interpret fitted statistical models. The SAS programs and data sets are available online.

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Statistical Approaches for Epidemiology

This textbook provides the basic concepts of epidemiology while preparing readers with the skills of applying statistical tools in real-life situations. Students, in general, struggle with statistical theories and their practical applications. This book makes statistical concepts easy to understand by focusing on real-life examples, case studies, and exercises. It also provides step-by-step guides for data analysis and interpretation using standard statistical software such as SPSS, SAS, R, Python, and GIS as appropriate, illustrating the concepts. Through the book's 23 chapters, readers primarily learn how to apply statistical methods in epidemiological studies and problem-solving. Among the topics covered: Clinical Trials Epidemic Investigation and Control Geospatial Applications in Epidemiology Survival Analysis and Applications Using SAS and SPSS Systematic Review and Meta-Analysis: Evidence-based Decision-Making in Public Health Missing Data Imputation: A Practical Guide Artificial Intelligence and Machine Learning Multivariate Linear Regression and Logistics Regression Analysis Using SAS Each chapter is written by eminent scientists and experts worldwide, including contributors from institutions in the United States, Canada, Bangladesh, India, Hong Kong, Malaysia, and the Middle East. Statistical Approaches for Epidemiology: From Concept to Application is an all-in-one book that serves as an essential text for graduate students, faculty, instructors, and researchers in public health and other branches of health sciences, as well as a useful resource for health researchers in industry, public health and health department professionals, health practitioners, and health research organizations and non-governmental organizations. The book also will be helpful for graduate students and faculty in related disciplines such as data science, nursing, social work, environmental health, occupational health, computer science, statistics, and biology.

SAS Programming in the Pharmaceutical Industry

This real-world reference for clinical trial SAS programming is packed with solutions that can be applied day-to-day problems. Organized to reflect the statistical programmers workflow, this user-friendly text begins with an introduction to the working environment, then presents chapters on importing and massaging data into analysis data sets, producing clinical trial output, and exporting data.

Implementing CDISC Using SAS

For decades researchers and programmers have used SAS to analyze, summarize, and report clinical trial data. Now Chris Holland and Jack Shostak have updated their popular Implementing CDISC Using SAS, the first comprehensive book on applying clinical research data and metadata to the Clinical Data Interchange Standards Consortium (CDISC) standards. Implementing CDISC Using SAS: An End-to-End Guide, Revised Second Edition, is an all-inclusive guide on how to implement and analyze the Study Data Tabulation Model (SDTM) and the Analysis Data Model (ADaM) data and prepare clinical trial data for regulatory submission. Updated to reflect the 2017 FDA mandate for adherence to CDISC standards, this new edition covers creating and using metadata, developing conversion

specifications, implementing and validating SDTM and ADaM data, determining solutions for legacy data conversions, and preparing data for regulatory submission. The book covers products such as Base SAS, SAS Clinical Data Integration, and the SAS Clinical Standards Toolkit, as well as JMP Clinical. Topics included in this edition include an implementation of the Define-XML 2.0 standard, new SDTM domains, validation with Pinnacle 21 software, event narratives in JMP Clinical, STDM and ADAM metadata spreadsheets, and of course new versions of SAS and JMP software. The second edition was revised to add the latest C-Codes from the most recent release as well as update the make_define macro that accompanies this book in order to add the capability to handle C-Codes. The metadata spreadsheets were updated accordingly. Any manager or user of clinical trial data in this day and age is likely to benefit from knowing how to either put data into a CDISC standard or analyzing and finding data once it is in a CDISC format. If you are one such person--a data manager, clinical and/or statistical programmer, biostatistician, or even a clinician--then this book is for you.

Introductory Adaptive Trial Designs

All the Essentials to Start Using Adaptive Designs in No TimeCompared to traditional clinical trial designs, adaptive designs often lead to increased success rates in drug development at reduced costs and time. Introductory Adaptive Trial Designs: A Practical Guide with R motivates newcomers to quickly and easily grasp the essence of adaptive desig

Multivariable Analysis

How to perform and interpret multivariable analysis, using plain language rather than complex derivations.

Adaptive Design Theory and Implementation Using SAS and R, Second Edition

Get Up to Speed on Many Types of Adaptive Designs Since the publication of the first edition, there have been remarkable advances in the methodology and application of adaptive trials. Incorporating many of these new developments, Adaptive Design Theory and Implementation Using SAS and R, Second Edition offers a detailed framework to understand the use of various adaptive design methods in clinical trials. New to the Second Edition Twelve new chapters covering blinded and semi-blinded sample size reestimation design, pick-the-winners design, biomarker-informed adaptive design, Bayesian designs, adaptive multiregional trial design, SAS and R for group sequential design, and much more More analytical methods for K-stage adaptive designs, multiple-endpoint adaptive design, survival modeling, and adaptive treatment switching New material on sequential parallel designs with rerandomization and the skeleton approach in adaptive dose-escalation trials Twenty new SAS macros and R functions Enhanced end-of-chapter problems that give readers hands-on practice addressing issues encountered in designing real-life adaptive trials Covering even more adaptive designs, this book provides biostatisticians, clinical scientists, and regulatory reviewers with up-to-date details on this innovative area in pharmaceutical research and development. Practitioners will be able to improve the efficiency of their trial design, thereby reducing the time and cost of drug development.

Common Statistical Methods for Clinical Research with SAS Examples, Third Edition

Glenn Walker and Jack Shostak's Common Statistical Methods for Clinical Research with SAS Examples, Third Edition, is a thoroughly updated edition of the popular introductory statistics book for clinical researchers. This new edition has been extensively updated to include the use of ODS graphics in numerous examples as well as a new emphasis on PROC MIXED. Straightforward and easy to use as either a text or a reference, the book is full of practical examples from clinical research to illustrate both statistical and SAS methodology. Each example is worked out completely, step by step, from the raw data. Common Statistical Methods for Clinical Research with SAS Examples, Third Edition, is an applications book with minimal theory. Each section begins with an overview helpful to nonstatisticians and then drills down into details that will be valuable to statistical analysts and programmers. Further details, as well as bonus information and a guide to further reading, are presented in the extensive appendices. This text is a one-source guide for statisticians that documents the use of the tests used most often in clinical research, with assumptions, details, and some tricks--all in one place. This book is part of the SAS Press program.

The Prevention and Treatment of Missing Data in Clinical Trials

Randomized clinical trials are the primary tool for evaluating new medical interventions. Randomization provides for a fair comparison between treatment and control groups, balancing out, on average, distributions of known and unknown factors among the participants. Unfortunately, these studies often lack a substantial percentage of data. This missing data reduces the benefit provided by the randomization and introduces potential biases in the comparison of the treatment groups. Missing data can arise for a variety of reasons, including the inability or unwillingness of participants to meet appointments for evaluation. And in some studies, some or all of data collection ceases when participants discontinue study treatment. Existing guidelines for the design and conduct of clinical trials, and the analysis of the resulting data, provide only limited advice on how to handle missing data. Thus, approaches to the analysis of data with an appreciable amount of missing values tend to be ad hoc and variable. The Prevention and Treatment of Missing Data in Clinical Trials concludes that a more principled approach to design and analysis in the presence of missing data is both needed and possible. Such an approach needs to focus on two critical elements: (1) careful design and conduct to limit the amount and impact of missing data and (2) analysis that makes full use of information on all randomized participants and is based on careful attention to the assumptions about the nature of the missing data underlying estimates of treatment effects. In addition to the highest priority recommendations, the book offers more detailed recommendations on the conduct of clinical trials and techniques for analysis of trial data.

Longitudinal Data Analysis

"This book provides accessible treatment to state-of-the-art approaches to analyzing longitudinal studies. Comprehensive coverage of the most popular analysis tools allows readers to pick and choose the techniques that best fit their research. The analyses are illustrated with examples from 12 major longitudinal data sets including practical information about their content and design. Illustrations from popular software packages offer tips on how to interpret the results. Each chapter features suggested readings fur further study and a list of articles that further illustrate how to implement the analysis and report the results. An accompanying website provides syntax examples for several software packages for each of the chapter examples. Although many of the examples address health or social science questions related to aging, readers from other disciplines will find the analyses relevant to their work. In addition to demonstrating statistical analysis of longitudinal data, the book shows how to interpret and analyze the results within the context of the research design. Although most chapters emphasize the use of large studies collected over long term periods, much of the book is also relevant to researchers who analyze data collected in shorter time periods. The book opens with issues related to using publicly available data sets including a description of the goals, designs, and measures of the data. The next 10 chapters provide non-technical, practical introductions to the concepts and issues relevant to longitudinal analysis, including: weighting samples and adjusting designs for longitudinal studies; missing data and attrition; measurement issues related to longitudinal research; the use of ANOVA and regression for averaging change over time; mediation analysis for analyzing causal processes; growth curve models using multilevel regression; longitudinal hypotheses using structural equation modeling (SEM); latent growth curve models for evaluating individual trajectories of change; dynamic SEM models of change; and survival (event) analysis. Examples from longitudinal data sets such as the Health and Retirement Study, the Longitudinal Study of Aging, and Established Populations for Epidemiologic Studies of the Elderly as well as international data sets such as the Canadian National Population Health Survey and the English Longitudinal Study of Aging, illustrate key concepts. An ideal supplement for graduate level courses on data analysis and/or longitudinal modeling taught in psychology, gerontology, human development, family studies, medicine, sociology, social work, and other behavioral, social, and health sciences, this multidisciplinary book will also appeal to researchers in these fields."--

SAS Programming in the Pharmaceutical Industry, Second Edition

This comprehensive resource provides on-the-job training for statistical programmers who use SAS in the pharmaceutical industry This one-stop resource offers a complete review of what entry- to intermediate-level statistical programmers need to know in order to help with the analysis and reporting of clinical trial data in the pharmaceutical industry. SAS Programming in the Pharmaceutical Industry, Second Edition begins with an introduction to the pharmaceutical industry and the work environment of a statistical programmer. Then it gives a chronological explanation of what you need to know to do the job. It includes information on importing and massaging data into analysis data sets, producing clinical trial output, and exporting data. This edition has been updated for SAS 9.4, and it features new graphics

as well as all new examples using CDISC SDTM or ADaM model data structures. Whether you're a novice seeking an introduction to SAS programming in the pharmaceutical industry or a junior-level programmer exploring new approaches to problem solving, this real-world reference guide offers a wealth of practical suggestions to help you sharpen your skills. This book is part of the SAS Press program.

Sample Size Calculations in Clinical Research

Praise for the Second Edition: "... this is a useful, comprehensive compendium of almost every possible sample size formula. The strong organization and carefully defined formulae will aid any researcher designing a study." -Biometrics "This impressive book contains formulae for computing sample size in a wide range of settings. One-sample studies and two-sample comparisons for quantitative, binary, and time-to-event outcomes are covered comprehensively, with separate sample size formulae for testing equality, non-inferiority, and equivalence. Many less familiar topics are also covered ..." – Journal of the Royal Statistical Society Sample Size Calculations in Clinical Research, Third Edition presents statistical procedures for performing sample size calculations during various phases of clinical research and development. A comprehensive and unified presentation of statistical concepts and practical applications, this book includes a well-balanced summary of current and emerging clinical issues, regulatory requirements, and recently developed statistical methodologies for sample size calculation. Features: Compares the relative merits and disadvantages of statistical methods for sample size calculations Explains how the formulae and procedures for sample size calculations can be used in a variety of clinical research and development stages Presents real-world examples from several therapeutic areas, including cardiovascular medicine, the central nervous system, anti-infective medicine, oncology, and women's health Provides sample size calculations for dose response studies, microarray studies, and Bayesian approaches This new edition is updated throughout, includes many new sections, and five new chapters on emerging topics: two stage seamless adaptive designs, cluster randomized trial design, zero-inflated Poisson distribution, clinical trials with extremely low incidence rates, and clinical trial simulation.

Categorical Data Analysis Using SAS, Third Edition

Statisticians and researchers will find this book, newly updated for SAS/STAT 12.1, to be a useful discussion of categorical data analysis techniques as well as an invaluable aid in applying these methods with SAS.

An Introduction to Statistics in Early Phase Trials

All new medicines and devices undergo early phase trials to assess, interpret and better understand their efficacy, tolerability and safety. An Introduction to Statistics in Early Phase Trials describes the practical design and analysis of these important early phase clinical trials and provides the crucial statistical basis for their interpretation. It clearly and concisely provides an overview of the most common types of trials undertaken in early phase clinical research and explains the different methodologies used. The impact of statistical technologies on clinical development and the statistical and methodological basis for making clinical and investment decisions are also explained. Conveys key ideas in a concise manner understandable by non-statisticians Explains how to optimise designs in a constrained or fixed resource setting Discusses decision making criteria at the end of Phase II trials Highlights practical day-to-day issues and reporting of early phase trials An Introduction to Statistics in Early Phase Trials is an essential guide for all researchers working in early phase clinical trial development, from clinical pharmacologists and pharmacokineticists through to clinical investigators and medical statisticians. It is also a valuable reference for teachers and students of pharmaceutical medicine learning about the design and analysis of clinical trials.

Designing Clinical Research

Designing Clinical Research sets the standard for providing a practical guide to planning, tabulating, formulating, and implementing clinical research, with an easy-to-read, uncomplicated presentation. This edition incorporates current research methodology—including molecular and genetic clinical research—and offers an updated syllabus for conducting a clinical research workshop. Emphasis is on common sense as the main ingredient of good science. The book explains how to choose well-focused research questions and details the steps through all the elements of study design, data collection,

quality assurance, and basic grant-writing. All chapters have been thoroughly revised, updated, and made more user-friendly.