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KEY=PAPERS - CRANE CARLY

Applied Statistics in Biomedicine and Clinical Trials

Design

Selected Papers from 2013 ICSA/ISBS Joint Statistical Meetings

Springer This volume is a unique combination of papers that cover critical topics in biostatistics from academic, government, and industry perspectives. The 6 sections cover Bayesian methods in biomedical research; Diagnostic medicine and classification; Innovative Clinical Trials Design; Modelling and Data Analysis; Personalized Medicine; and Statistical Genomics. The real world applications are in clinical trials, diagnostic medicine and genetics. The peer-reviewed contributions were solicited and selected from some 400 presentations at the annual meeting of the International Chinese Statistical Association (ICSA), held with the International Society for Biopharmaceutical Statistics (ISBS). The conference was held in Bethesda in June 2013, and the material has been subsequently edited and expanded to cover the most recent developments.

Biopharmaceutical Applied Statistics Symposium

Volume 2 Biostatistical Analysis of Clinical Trials

Springer This BASS book Series publishes selected high-quality papers reflecting recent advances in the design and biostatistical analysis of biopharmaceutical experiments – particularly biopharmaceutical clinical trials. The papers were selected from invited presentations at the Biopharmaceutical Applied Statistics Symposium (BASS), which was founded by the first Editor in 1994 and has since become the premier international conference in biopharmaceutical statistics. The primary aims of the BASS are: 1) to raise funding to support graduate students in biostatistics programs, and 2) to provide an opportunity for professionals engaged in pharmaceutical drug research and development to share insights into solving the problems they encounter. The BASS book series is initially divided into three volumes addressing: 1) Design of Clinical Trials; 2) Biostatistical Analysis of Clinical Trials; and 3) Pharmaceutical Applications. This book is the second of the 3-volume book series. The topics covered include: Statistical Approaches

to the Meta-analysis of Randomized Clinical Trials, Collaborative Targeted Maximum Likelihood Estimation to Assess Causal Effects in Observational Studies, Generalized Tests in Clinical Trials, Discrete Time-to-event and Score-based Methods with Application to Composite Endpoint for Assessing Evidence of Disease Activity-Free , Imputing Missing Data Using a Surrogate Biomarker: Analyzing the Incidence of Endometrial Hyperplasia, Selected Statistical Issues in Patient-reported Outcomes, Network Meta-analysis, Detecting Safety Signals Among Adverse Events in Clinical Trials, Applied Meta-analysis Using R, Treatment of Missing Data in Comparative Effectiveness Research, Causal Estimands: A Common Language for Missing Data, Bayesian Subgroup Analysis with Examples, Statistical Methods in Diagnostic Devices, A Question-Based Approach to the Analysis of Safety Data, Analysis of Two-stage Adaptive Seamless Trial Design, and Multiplicity Problems in Clinical Trials – A Regulatory Perspective.

Applied Categorical Data Analysis and Translational Research

John Wiley & Sons An updated treatment of categorical data analysis in the biomedical sciences that now explores applications to translational research Thoroughly updated with the latest advances in the field, Applied Categorical Data Analysis and Translational Research, Second Edition maintains the accessible style of its predecessor while also exploring the importance of translational research as it relates to basic scientific findings within clinical practice. With its easy–to–follow style, updated coverage of major methodologies, and broadened scope of coverage, this new edition provides an accessible guide to statistical methods involving categorical data and the steps to their application in problem solving in the biomedical sciences. Delving even further into the applied direction, this update offers many real–world examples from biomedicine, epidemiology, and public health along with detailed case studies taken straight from modern research in these fields. Additional features of the Second Edition include: A new chapter on the relationship between translational research and categorical data, focusing on design study, bioassay, and Phase I and Phase II clinical trials A new chapter on categorical data and diagnostic medicine, with coverage of the diagnostic process, prevalence surveys, the ROC function and ROC curve, and important statistical considerations A revised chapter on logistic regression models featuring an updated treatment of simple and multiple regression analysis An added section on quantal bioassays Each chapter features updated and new exercise sets along with numerous graphs that demonstrate the highly visual nature of the topic. A related Web site features the book′s examples as well as additional data sets that can be worked with using SAS® software. The only book of its kind to provide balanced coverage of methods for both categorical data and translational research, Applied Categorical Data Analysis and Translational Research, Second Edition is an excellent book for courses on applied statistics and biostatistics at the

upper–undergraduate and graduate levels. It is also a valuable reference for researchers and practitioners in the biomedical and public health fields.

Analysis of Clinical Trials Using SAS

A Practical Guide, Second Edition

SAS Institute 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.

Modern Approaches to Clinical Trials Using SAS:

Classical, Adaptive, and Bayesian Methods

SAS Institute This book covers domains of modern clinical trial design: classical, group sequential, adaptive, and Bayesian methods applicable to and 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, it covers topics including: dose-response and dose-escalation designs; sequential methods to stop trials early for overwhelming efficacy, safety, or futility; Bayesian designs incorporating historical data; adaptive sample size re-estimation and randomization to allocate subjects to effective treatments; population enrichment designs. Methods are illustrated using clinical trials from diverse therapeutic areas, including dermatology, endocrinology, infectious disease, neurology, oncology and rheumatology. --

Sharing Clinical Trial Data

Maximizing Benefits, Minimizing Risk

National Academies Press 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.

Group-Sequential Clinical Trials with Multiple Co-Objectives

Springer This book focuses on group sequential methods for clinical trials with co-primary endpoints based on the decision-making frameworks for: (1) rejecting the null hypothesis (stopping for efficacy), (2) rejecting the alternative hypothesis (stopping for futility), and (3) rejecting the null or alternative hypothesis (stopping for either futility or efficacy), where the trial is designed to evaluate whether the intervention is superior to the control on all endpoints. For assessing futility, there are two fundamental approaches, i.e., the decision to stop for futility based on the conditional probability of rejecting the null hypothesis, and the other based on stopping boundaries using group sequential methods. In this book, the latter approach is discussed. The book also briefly deals with the group sequential methods for clinical trials designed to evaluate whether the intervention is superior to the control on at least one endpoint. In addition, the book describes sample size recalculation and the resulting effect on power and type I error rate. The book also describes group sequential strategies for three-arm clinical trials to demonstrate the non-inferiority of experimental intervention to actively control and to assess the assay sensitivity to placebo control.

New Developments in Statistical Modeling, Inference and Application

Selected Papers from the 2014 ICSA/KISS Joint Applied

Statistics Symposium in Portland, OR

Springer The papers in this volume represent the most timely and advanced contributions to the 2014 Joint Applied Statistics Symposium of the International Chinese Statistical Association (ICSA) and the Korean International Statistical Society (KISS), held in Portland, Oregon. The contributions cover new developments in statistical modeling and clinical research: including model development, model checking, and innovative clinical trial design and analysis. Each paper was peer-reviewed by at least two referees and also by an editor. The conference was attended by over 400 participants from academia, industry, and government agencies around the world, including from North America, Asia, and Europe. It offered 3 keynote speeches, 7 short courses, 76 parallel scientific sessions, student paper sessions, and social events.

Design and Analysis of Subgroups with Biopharmaceutical Applications

Springer Nature This book provides an overview of the theories and applications on subgroups in the biopharmaceutical industry. Drawing from a range of expert perspectives in academia and industry, this collection offers an overarching dialogue about recent advances in biopharmaceutical applications, novel statistical and methodological developments, and potential future directions. The volume covers topics in subgroups in clinical trial design; subgroup identification and personalized medicine; and general issues in subgroup analyses, including regulatory ones. Included chapters present current methods, theories, and case applications in the diverse field of subgroup application and analysis. Offering timely perspectives from a range of authoritative sources, the volume is designed to have wide appeal to professionals in the pharmaceutical industry and to graduate students and researchers in academe and government.

Contemporary Biostatistics with Biopharmaceutical

Applications

Springer This edited volume presents current research in biostatistics with emphasis on biopharmaceutical applications. Featuring contributions presented at the 2017 ICSA Applied Statistics Symposium held in Chicago, IL on June 25 to 28, 2017, this book explores timely topics that have a high potential impact on statistical methodology and future research in biostatistics and biopharmaceuticals. The theme of this conference was Statistics for a New Generation: Challenges and Opportunities, in recognition of the advent of a new generation of statisticians. The conference attracted statisticians working in academia, government, and industry; domestic and international statisticians. From the conference, the editors selected 28 high-quality presentations and invited the speakers to prepare full chapters for this book. These contributions are divided into four parts: Part I Biostatistical Methodology, Part II Statistical Genetics and Bioinformatics, Part III Regulatory Statistics, and Part IV Biopharmaceutical Research and Applications. Featuring contributions on topics such as statistics in genetics, bioinformatics, biostatistical methodology, and statistical computing, this book is beneficial to researchers, academics, practitioners and policy makers in biostatistics and biopharmaceuticals.

Quantitative Methods in Pharmaceutical Research and Development

Concepts and Applications

Springer Nature This contributed volume presents an overview of concepts, methods, and applications used in several quantitative areas of drug research, development, and marketing. Chapters bring together the theories and applications of various disciplines, allowing readers to learn more about quantitative fields, and to better recognize the differences between them. Because it provides a thorough overview, this will serve as a self-contained resource for readers interested in the pharmaceutical industry, and the quantitative methods that serve as its foundation. Specific disciplines covered include: Biostatistics Pharmacometrics Genomics Bioinformatics Pharmacoepidemiology Commercial analytics Operational analytics Quantitative Methods in Pharmaceutical Research and Development is ideal for undergraduate students interested in learning about real-world applications of quantitative methods, and the potential career options open to them. It will also be of interest to experts working in these areas.

Modern Statistical Methods for Health Research

Springer This book brings together the voices of leading experts in the frontiers of biostatistics, biomedicine, and the health sciences to discuss the statistical procedures, useful methods, and novel applications in biostatistics research. It also includes discussions of potential future directions of biomedicine and new statistical developments for health research, with the intent of stimulating research and fostering the interactions of scholars across health research related disciplines. Topics covered include: Health data analysis and applications to EHR data Clinical trials, FDR, and applications in health science Big network analytics and its applications in GWAS Survival analysis and functional data analysis Graphical modelling in genomic studies The book will be valuable to data scientists and statisticians who are working in biomedicine and health, other practitioners in the health sciences, and graduate students and researchers in biostatistics and health.

Proceedings of the Tenth International Conference on Management Science and Engineering Management

Springer This book presents the proceedings of the Tenth International Conference on Management Science and Engineering Management (ICMSEM2016) held from August 30 to September 02, 2016 at Baku, Azerbaijan and organized by the International Society of Management Science and Engineering Management, Sichuan University (Chengdu, China) and Ministry of Education of Azerbaijan. The aim of conference was to foster international research collaborations in management science and engineering management as well as to provide a forum to present current research findings. The presented papers were selected and reviewed by the Program Committee, made up of respected experts in the area of management science and engineering management from around the globe. The contributions focus on identifying management science problems in engineering, innovatively using management theory and methods to solve engineering problems effectively and establishing novel management theories and methods to address new engineering management issues.

Controversial Statistical Issues in Clinical Trials

CRC Press In clinical trial practice, controversial statistical issues inevitably occur regardless of the compliance with good statistical practice and good clinical practice. But by identifying the causes of the issues and correcting them, the study objectives of clinical trials can be better achieved. Controversial Statistical Issues in Clinical Trials covers commonly encountered controversial statistical issues in clinical trials and, whenever possible, makes recommendations to resolve these problems. The book focuses on issues occurring at various stages of clinical research and development, including early-phase clinical development (such as bioavailability/bioequivalence), bench-to-bedside translational research, and late-phase clinical development. Numerous examples illustrate the impact of these issues on the evaluation of the safety and efficacy of the test treatment under investigation. The author also offers recommendations regarding possible resolutions of the problems. Written by one of the preeminent experts in the field, this book provides a useful desk reference and state-of-the art examination of problematic issues in clinical trials for scientists in the pharmaceutical industry, medical/statistical reviewers in government regulatory agencies, and researchers and students in academia.

Clinical Trial Data Analysis Using R

CRC Press 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.

Applied Statistical Methods

ISGES 2020, Pune, India, January 2–4

Springer Nature

Data and Safety Monitoring Committees in Clinical Trials

CRC Press Focusing on the practical clinical and statistical issues that arise in pharmaceutical industry trials, this book summarizes the author’s experience in serving on many data monitoring committees (DMCs) and in heading up a contract research organization that provided statistical support to nearly seventy-five DMCs. It explains the difference in DMC operations between the pharmaceutical industry and National Institutes of Health (NIH)-sponsored trials. Leading you through the types of reports for adverse events and lab values, the author presents the statistical requirements of data monitoring committees and gives advice on how statisticians can best interact with physician members of these committees. He also shows how physicians think differently about safety data than statisticians, proving that both views are needed.

Computational Methods in Biomedical Research

CRC Press Continuing advances in biomedical research and statistical methods call for a constant stream of updated, cohesive accounts of new developments so that the methodologies can be properly implemented in the biomedical field. Responding to this need, Computational Methods in Biomedical Research explores important current and emerging computational statistical methods that are used in biomedical research. Written by active researchers in the field, this authoritative collection covers a wide range of topics. It introduces each topic at a basic level, before moving on to more advanced discussions of applications. The book begins with microarray data analysis, machine learning techniques, and mass spectrometry-based protein profiling. It then uses state space models to predict US cancer mortality rates and provides an overview of the application of multistate models in analyzing multiple failure times. The book also describes various Bayesian techniques, the sequential monitoring of randomization tests, mixed-effects models, and the classification rules for repeated measures data. The volume concludes with estimation methods for analyzing longitudinal data. Supplying the knowledge necessary to perform sophisticated statistical analyses, this reference is a must-have for

anyone involved in advanced biomedical and pharmaceutical research. It will help in the quest to identify potential new drugs for the treatment of a variety of diseases.

Clinical Trial Methodology

CRC Press Now viewed as its own scientific discipline, clinical trial methodology encompasses the methods required for the protection of participants in a clinical trial and the methods necessary to provide a valid inference about the objective of the trial. Drawing from the authors' courses on the subject as well as the first author's more than 30 years working in the pharmaceutical industry, Clinical Trial Methodology emphasizes the importance of statistical thinking in clinical research and presents the methodology as a key component of clinical research. From ethical issues and sample size considerations to adaptive design procedures and statistical analysis, the book first covers the methodology that spans every clinical trial regardless of the area of application. Crucial to the generic drug industry, bioequivalence clinical trials are then discussed. The authors describe a parallel bioequivalence clinical trial of six formulations incorporating group sequential procedures that permit sample size re-estimation. The final chapters incorporate real-world case studies of clinical trials from the authors' own experiences. These examples include a landmark Phase III clinical trial involving the treatment of duodenal ulcers and Phase III clinical trials that contributed to the first drug approved for the treatment of Alzheimer's disease. Aided by the U.S. FDA, the U.S. National Institutes of Health, the pharmaceutical industry, and academia, the area of clinical trial methodology has evolved over the last six decades into a scientific discipline. This guide explores the processes essential for developing and conducting a quality clinical trial protocol and providing quality data collection, biostatistical analyses, and a clinical study report, all while maintaining the highest standards of ethics and excellence.

Bayesian Adaptive Methods for Clinical Trials

CRC Press Already popular in the analysis of medical device trials, adaptive Bayesian designs are increasingly being used in drug development for a wide variety of diseases and conditions, from Alzheimer's disease and multiple sclerosis to obesity, diabetes, hepatitis C, and HIV. Written by leading pioneers of Bayesian clinical trial designs, Bayesian Adaptive Methods for Clinical Trials explores the growing role of Bayesian thinking in the rapidly changing world of clinical trial analysis. The book first summarizes the current state of clinical trial design and analysis and introduces the main ideas and potential benefits of a Bayesian alternative. It then gives an overview of basic Bayesian methodological and computational tools needed for Bayesian clinical trials. With a focus on Bayesian designs that achieve good power and Type I error, the next chapters present Bayesian tools useful in early (Phase I) and

middle (Phase II) clinical trials as well as two recent Bayesian adaptive Phase II studies: the BATTLE and ISPY-2 trials. In the following chapter on late (Phase III) studies, the authors emphasize modern adaptive methods and seamless Phase II–III trials for maximizing information usage and minimizing trial duration. They also describe a case study of a recently approved medical device to treat atrial fibrillation. The concluding chapter covers key special topics, such as the proper use of historical data, equivalence studies, and subgroup analysis. For readers involved in clinical trials research, this book significantly updates and expands their statistical toolkits. The authors provide many detailed examples drawing on real data sets. The R and WinBUGS codes used throughout are available on supporting websites. Scott Berry talks about the book on the CRC Press YouTube Channel.

Applied Statistical Designs for the Researcher

CRC Press Showcasing a discussion of the experimental process and a review of basic statistics, this volume provides methodologies to identify general data distribution, skewness, and outliers. It features a unique classification of the nonparametric analogs of their parametric counterparts according to the strength of the collected data. Applied Statistical Designs for the Researcher discusses three varieties of the Student t test, including a comparison of two different groups with different variances; two groups with the same variance; and a matched, paired group. It introduces the analysis of variance and Latin Square designs and presents screening approaches to comparing two factors and their interactions.

Multiregional Clinical Trials for Simultaneous Global New Drug Development

CRC Press In a global clinical development strategy, multiregional clinical trials (MRCTs) are vital in the development of innovative medicines. Multiregional Clinical Trials for Simultaneous Global New Drug Development presents a comprehensive overview on the current status of conducting MRCTs in clinical development. International experts from academia, in

Design and Analysis of Clinical Trials with Time-to-Event

Endpoints

CRC Press Using time-to-event analysis methodology requires careful definition of the event, censored observation, provision of adequate follow-up, number of events, and independence or "noninformativeness" of the censoring mechanisms relative to the event. Design and Analysis of Clinical Trials with Time-to-Event Endpoints provides a thorough presentation of the design, monitoring, analysis, and interpretation of clinical trials in which time-to-event is of critical interest. After reviewing time-to-event endpoint methodology, clinical trial issues, and the design and monitoring of clinical trials, the book focuses on inferential analysis methods, including parametric, semiparametric, categorical, and Bayesian methods; an alternative to the Cox model for small samples; and estimation and testing for change in hazard. It then presents descriptive and graphical methods useful in the analysis of time-to-event endpoints. The next several chapters explore a variety of clinical trials, from analgesic, antibiotic, and antiviral trials to cardiovascular and cancer prevention, prostate cancer, astrocytoma brain tumor, and chronic myelogonous leukemia trials. The book then covers areas of drug development, medical practice, and safety assessment. It concludes with the design and analysis of clinical trials of animals required by the FDA for new drug applications. Drawing on the expert contributors’ experiences working in biomedical research and clinical drug development, this comprehensive resource covers an array of time-to-event methods and explores an assortment of real-world applications.

Randomized Clinical Trials of Nonpharmacological Treatments

CRC Press Nonpharmacological treatments include a wide variety of treatments such as surgery, technical procedures, implantable and non-implantable devices, rehabilitation, psychotherapy, and behavioral interventions. Unlike pharmacological treatments, these have no specific requirements for approval. Consequently, they can be widely proposed in clinical practice but may not have been adequately evaluated. This situation is an important barrier for the evaluation of the beneficial effects of these treatments and the conduct of clinical trials. Randomized Clinical Trials of Nonpharmacologic Treatments focuses on the methods for assessing nonpharmacological treatments, highlighting specific issues and trial design. Features: Chapters written by international experts in the field Highlights specific issues in assessing nonpharmacological treatments in trials including: how to overcome the difficulties of blinding patients, care providers, and outcome assessors the complexity of the intervention, the learning curve, and the clustering

effect placebos that can be used issues of assessing harm and assessing the applicability of trials Presents a variety of trial designs for nonpharmacological treatments—including cluster randomized controlled trials, expertise-based trials, pragmatic trials, and nonrandomized trials. Provides several examples of the planning, conduct, analyses, and reporting of trials in different fields, including surgery, technical interventions, medical devices, rehabilitation, psychotherapy, and behavioral interventions. Providing practical examples that underline these issues and solutions, this book is one of the first to exclusively explore this topic, discussing various categories of treatments, from surgical procedures to psychotherapy.

Adaptive Design Methods in Clinical Trials

CRC Press Although adaptive design methods are flexible and useful in clinical research, little or no regulatory guidelines are available. One of the first books on the topic, Adaptive Design Methods in Clinical Trials presents the principles and methodologies in adaptive design and analysis that pertain to adaptations made to trial or statistical procedures

Multiple Testing Problems in Pharmaceutical Statistics

CRC Press Useful Statistical Approaches for Addressing Multiplicity IssuesIncludes practical examples from recent trials Bringing together leading statisticians, scientists, and clinicians from the pharmaceutical industry, academia, and regulatory agencies, Multiple Testing Problems in Pharmaceutical Statistics explores the rapidly growing area of multiple c

Statistical Evaluation of Diagnostic Performance

Topics in ROC Analysis

CRC Press Statistical evaluation of diagnostic performance in general and Receiver Operating Characteristic (ROC) analysis in particular are important for assessing the performance of medical tests and statistical classifiers, as well as for evaluating predictive models or algorithms. This book presents innovative approaches in ROC analysis, which are relevant to a wide variety of applications, including medical imaging, cancer research, epidemiology, and bioinformatics. Statistical Evaluation of Diagnostic Performance: Topics in ROC Analysis covers areas including monotone-transformation techniques in parametric ROC analysis, ROC methods for combined and pooled biomarkers, Bayesian hierarchical transformation models, sequential designs and inferences in the ROC setting, predictive

modeling, multireader ROC analysis, and free-response ROC (FROC) methodology. The book is suitable for graduate-level students and researchers in statistics, biostatistics, epidemiology, public health, biomedical engineering, radiology, medical imaging, biomedical informatics, and other closely related fields. Additionally, clinical researchers and practicing statisticians in academia, industry, and government could benefit from the presentation of such important and yet frequently overlooked topics.

Dose Finding by the Continual Reassessment Method

CRC Press As clinicians begin to realize the important role of dose-finding in the drug development process, there is an increasing openness to "novel" methods proposed in the past two decades. In particular, the Continual Reassessment Method (CRM) and its variations have drawn much attention in the medical community, though it has yet to become a commonplace tool. To overcome the status quo in phase I clinical trials, statisticians must be able to design trials using the CRM in a timely and reproducible manner. A self-contained theoretical framework of the CRM for researchers and graduate students who set out to learn and do research in the CRM and dose-finding methods in general, Dose Finding by the Continual Reassessment Method features: Real clinical trial examples that illustrate the methods and techniques throughout the book Detailed calibration techniques that enable biostatisticians to design a CRM in timely manner Limitations of the CRM are outlined to aid in correct use of method This book supplies practical, efficient dose-finding methods based on cutting edge statistical research. More than just a cookbook, it provides full, unified coverage of the CRM in addition to step-by-step guidelines to automation and parameterization of the methods used on a regular basis. A detailed exposition of the calibration of the CRM for applied statisticians working with dose-finding in phase I trials, the book focuses on the R package ‘dfcrm’ for the CRM and its major variants. The author recognizes clinicians’ skepticism of model-based designs, and addresses their concerns that the time, professional, and computational resources necessary for accurate model-based designs can be major bottlenecks to the widespread use of appropriate dose-finding methods in phase I practice. The theoretically- and empirically-based methods in Dose Finding by the Continual Reassessment Method will lessen the statistician’s burden and encourage the continuing development and implementation of model-based dose-finding methods.

Design and Analysis of Non-Inferiority Trials

CRC Press The increased use of non-inferiority analysis has been accompanied by a proliferation of research on the design and analysis of non-inferiority studies. Using examples from real clinical trials, Design and Analysis of Non-Inferiority Trials brings together this body of research and confronts the issues involved in the design of a non-inferiority trial. Each chapter begins with a non-technical

introduction, making the text easily understood by those without prior knowledge of this type of trial. Topics covered include: A variety of issues of non-inferiority trials, including multiple comparisons, missing data, analysis population, the use of safety margins, the internal consistency of non-inferiority inference, the use of surrogate endpoints, trial monitoring, and equivalence trials Specific issues and analysis methods when the data are binary, continuous, and time-to-event The history of non-inferiority trials and the design and conduct considerations for a non-inferiority trial The strength of evidence of an efficacy finding and how to evaluate the effect size of an active control therapy A comprehensive discussion on the purpose and issues involved with non-inferiority trials, Design and Analysis of Non-inferiority Trials will assist current and future scientists and statisticians on the optimal design of non-inferiority trials and in assessing the quality of non-inferiority comparisons done in practice.

Sample Size Calculations in Clinical Research, Second Edition

CRC Press Focusing on an integral part of pharmaceutical development, Sample Size Calculations in Clinical Research, Second Edition presents statistical procedures for performing sample size calculations during various phases of clinical research and development. It provides sample size formulas and procedures for testing equality, noninferiority/superiority, and equivalence. A comprehensive and unified presentation of statistical concepts and practical applications, this book highlights the interactions between clinicians and biostatisticians, includes a well-balanced summary of current and emerging clinical issues, and explores recently developed statistical methodologies for sample size calculation. Whenever possible, each chapter provides a brief history or background, regulatory requirements, statistical designs and methods for data analysis, real-world examples, future research developments, and related references. One of the few books to systematically summarize clinical research procedures, this edition contains new chapters that focus on three key areas of this field. Incorporating the material of this book in your work will help ensure the validity and, ultimately, the success of your clinical studies.

Advanced Bayesian Methods for Medical Test Accuracy

CRC Press Useful in many areas of medicine and biology, Bayesian methods are particularly attractive tools for the design of clinical trials and diagnostic tests, which are based on established information, usually from related previous studies. Advanced Bayesian Methods for Medical Test Accuracy begins with a review of the usual measures such as specificity, sensitivity, positive and negative

predictive value, and the area under the ROC curve. Then the scope expands to cover the more advanced topics of verification bias, diagnostic tests with imperfect gold standards, and those for which no gold standard is available. Promoting accuracy and efficiency of clinical trials, tests, and the diagnostic process, this book: Enables the user to efficiently apply prior information via a WinBUGS package Presents many ideas for the first time and goes far beyond the two standard references Integrates reader agreement with different modalities—X-ray, CT Scanners, and more—to study their effect on medical test accuracy Provides practical chapter-end problems Useful for graduate students and consulting statisticians working in the various areas of diagnostic medicine and study design, this practical resource introduces the fundamentals of programming and executing BUGS, giving readers the tools and experience to successfully analyze studies for medical test accuracy.

Monte Carlo Simulation for the Pharmaceutical Industry Concepts, Algorithms, and Case Studies

CRC Press Helping you become a creative, logical thinker and skillful "simulator," Monte Carlo Simulation for the Pharmaceutical Industry: Concepts, Algorithms, and Case Studies provides broad coverage of the entire drug development process, from drug discovery to preclinical and clinical trial aspects to commercialization. It presents the theories and methods needed to carry out computer simulations efficiently, covers both descriptive and pseudocode algorithms that provide the basis for implementation of the simulation methods, and illustrates real-world problems through case studies. The text first emphasizes the importance of analogy and simulation using examples from a variety of areas, before introducing general sampling methods and the different stages of drug development. It then focuses on simulation approaches based on game theory and the Markov decision process, simulations in classical and adaptive trials, and various challenges in clinical trial management and execution. The author goes on to cover prescription drug marketing strategies and brand planning, molecular design and simulation, computational systems biology and biological pathway simulation with Petri nets, and physiologically based pharmacokinetic modeling and pharmacodynamic models. The final chapter explores Monte Carlo computing techniques for statistical inference. This book offers a systematic treatment of computer simulation in drug development. It not only deals with the principles and methods of Monte Carlo simulation, but also the applications in drug development, such as statistical trial monitoring, prescription drug marketing, and molecular docking.

Advances in Clinical Trial Biostatistics

CRC Press From aspects of early trials to complex modeling problems, Advances in Clinical Trial Biostatistics summarizes current methodologies used in the design and analysis of clinical trials. Its chapters, contributed by internationally renowned methodologists experienced in clinical trials, address topics that include Bayesian methods for phase I clinical trials, adaptive two-stage clinical trials, and the design and analysis of cluster randomization trials, trials with multiple endpoints, and therapeutic equivalence trials. Other discussions explore Bayesian reporting, methods incorporating compliance in treatment evaluation, and statistical issues emerging from clinical trials in HIV infection.

Bayesian Missing Data Problems

EM, Data Augmentation and Noniterative Computation

CRC Press Bayesian Missing Data Problems: EM, Data Augmentation and Noniterative Computation presents solutions to missing data problems through explicit or noniterative sampling calculation of Bayesian posteriors. The methods are based on the inverse Bayes formulae discovered by one of the author in 1995. Applying the Bayesian approach to important real-world problems, the authors focus on exact numerical solutions, a conditional sampling approach via data augmentation, and a noniterative sampling approach via EM-type algorithms. After introducing the missing data problems, Bayesian approach, and posterior computation, the book succinctly describes EM-type algorithms, Monte Carlo simulation, numerical techniques, and optimization methods. It then gives exact posterior solutions for problems, such as nonresponses in surveys and cross-over trials with missing values. It also provides noniterative posterior sampling solutions for problems, such as contingency tables with supplemental margins, aggregated responses in surveys, zero-inflated Poisson, capture-recapture models, mixed effects models, right-censored regression model, and constrained parameter models. The text concludes with a discussion on compatibility, a fundamental issue in Bayesian inference. This book offers a unified treatment of an array of statistical problems that involve missing data and constrained parameters. It shows how Bayesian procedures can be useful in solving these problems.

Bayesian Analysis Made Simple

An Excel GUI for WinBUGS

CRC Press Although the popularity of the Bayesian approach to statistics has been growing for years, many still think of it as somewhat esoteric, not focused on practical issues, or generally too difficult to understand. Bayesian Analysis Made Simple is aimed at those who wish to apply Bayesian methods but either are not experts or do not have the time to create WinBUGS code and ancillary files for every analysis they undertake. Accessible to even those who would not routinely use Excel, this book provides a custom-made Excel GUI, immediately useful to those users who want to be able to quickly apply Bayesian methods without being distracted by computing or mathematical issues. From simple NLMs to complex GLMMs and beyond, Bayesian Analysis Made Simple describes how to use Excel for a vast range of Bayesian models in an intuitive manner accessible to the statistically savvy user. Packed with relevant case studies, this book is for any data analyst wishing to apply Bayesian methods to analyze their data, from professional statisticians to statistically aware scientists.

Frailty Models in Survival Analysis

CRC Press The concept of frailty offers a convenient way to introduce unobserved heterogeneity and associations into models for survival data. In its simplest form, frailty is an unobserved random proportionality factor that modifies the hazard function of an individual or a group of related individuals. Frailty Models in Survival Analysis presents a comprehensive overview of the fundamental approaches in the area of frailty models. The book extensively explores how univariate frailty models can represent unobserved heterogeneity. It also emphasizes correlated frailty models as extensions of univariate and shared frailty models. The author analyzes similarities and differences between frailty and copula models; discusses problems related to frailty models, such as tests for homogeneity; and describes parametric and semiparametric models using both frequentist and Bayesian approaches. He also shows how to apply the models to real data using the statistical packages of R, SAS, and Stata. The appendix provides the technical mathematical results used throughout. Written in nontechnical terms accessible to nonspecialists, this book explains the basic ideas in frailty modeling and statistical techniques, with a focus on real-world data application and interpretation of the results. By applying several models to the same data, it allows for the comparison of their advantages and limitations under varying model assumptions.

The book also employs simulations to analyze the finite sample size performance of the models.

Bayesian Modeling in Bioinformatics

CRC Press Bayesian Modeling in Bioinformatics discusses the development and application of Bayesian statistical methods for the analysis of high-throughput bioinformatics data arising from problems in molecular and structural biology and disease-related medical research, such as cancer. It presents a broad overview of statistical inference, clustering, and c

Medical Biostatistics, Second Edition

CRC Press Emphasizing statistical concepts used in medicine, the interpretation of methods, and applications, Medical Biostatistics, Second Edition shows how biostatistical methods are important tools in managing uncertainties in medicine and the health sciences. With coverage ranging from elementary topics, such as mean and standard deviation, to advanced approaches, such as logistic regression and multivariate methods, this edition is even more far-reaching in scope than its predecessor. New to the Second Edition Full chapters on clinical trials, observational studies, laboratory experiments, survival analysis, and logistic regression A new chapter on clinimetrics and evidence-based medicine Expanded discussions on epistemic uncertainties, crossover designs, equivalence trials and studies, hazard functions, and the log-rank test The introduction of research evidence, multilevel regression, classification, and regression trees at an elementary level Sample size formulas for relative risk, odds ratio, and survival studies Numerous additional examples from contemporary medical literature Numbered steps for the many procedures and remarks Requiring only high school algebra, this text enables a solid understanding of the statistical concepts required to critically examine medical literature, scientifically plan and carry out medical investigations, and meaningfully analyze data.

Measures of Interobserver Agreement and Reliability

CRC Press Measures of Interobserver Agreement and Reliability, Second Edition covers important issues related to the design and analysis of reliability and agreement studies. It examines factors affecting the degree of measurement errors in reliability generalization studies and characteristics influencing the process of diagnosing each subject in a reliabil

Translational Medicine

Strategies and Statistical Methods

CRC Press Examines Critical Decisions for Transitioning Lab Science to a Clinical Setting The development of therapeutic pharmaceutical compounds is becoming more expensive, and the success rates for getting such treatments approved for marketing and to the patients is decreasing. As a result, translational medicine (TM) is becoming increasingly important in the healthcare industry – a means of maximizing the consideration and use of information collected as compounds transition from initial lab discovery, through pre-clinical testing, early clinical trials, and late confirmatory studies that lead to regulatory approval of drug release to patients. Translational Medicine: Strategies and Statistical Methods suggests a process for transitioning from the initial lab discovery to the patient’s bedside with minimal disconnect and offers a comprehensive review of statistical design and methodology commonly employed in this bench-to-bedside research. Documents Alternative Research Approaches for Faster and More Accurate Data Judgment Calls Elaborating on how to introduce TM into clinical studies, this authoritative work presents a keen approach to building, executing, and validating statistical models that consider data from various phases of development. It also delineates a truly translational example to help bolster understanding of discussed concepts. This comprehensive guide effectively demonstrates how to overcome obstacles related to successful TM practice. It contains invaluable information for pharmaceutical scientists, research executives, clinicians, and biostatisticians looking to expedite successful implementation of this important process.