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Analytical Similarity Assessment in Biosimilar Product Development - Shein-Chung Chow 2018-09-03

This book focuses on analytical similarity assessment in biosimilar product development following the FDA's recommended stepwise approach for obtaining totality-of-the-evidence for approval of biosimilar products. It covers concepts such as the tiered approach for assessment of similarity of critical quality attributes in the manufacturing process of biosimilar products, models/methods like the statistical model for classification of critical quality attributes, equivalence tests for critical quality attributes in Tier 1 and the corresponding sample size requirements, current issues, and recent developments in analytical similarity assessment.

Sample Size Tables for Clinical Studies - David Machin 2011-08-26

This book provides statisticians and researchers with the statistical tools - equations, formulae and numerical tables - to design and plan clinical studies and carry out accurate, reliable and reproducible analysis of the data so obtained. There is no way around this as incorrect procedure in clinical studies means that the researcher's paper will not be accepted by a peer-reviewed journal. Planning and analysing clinical studies is a very complicated business and this book provides indispensible factual information. Please go to http://booksupport.wiley.com and enter 9781405146500 to easily download the supporting materials.

Sample Size Calculations in Clinical Research, Second Edition - Shein-Chung Chow 2007-08-22

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.

Elementary Bayesian Biostatistics - Lemuel A. Moye 2016-04-19

Bayesian analyses have made important inroads in modern clinical research due, in part, to the incorporation of the traditional tools of noninformative priors as well as the modern innovations of adaptive randomization and predictive power. Presenting an introductory perspective to modern Bayesian procedures, Elementary Bayesian Biostatistics explo

Sample Size Calculations for Clustered and Longitudinal Outcomes in Clinical Research - Chul Ahn 2014-12-09

Accurate sample size calculation ensures that clinical studies have adequate power to detect clinically meaningful effects. This results in the efficient use of resources and avoids exposing a disproportionate number of patients to experimental treatments caused by an overpowered study. Sample Size Calculations for Clustered and Longitudinal Outcomes in Clinical Research explains how to determine sample size for studies with correlated outcomes, which are widely implemented in medical, epidemiological, and behavioral studies. The book focuses on issues specific to the two types of correlated outcomes: longitudinal and clustered. For clustered studies, the authors provide sample size formulas that accommodate variable cluster sizes and within-cluster correlation. For longitudinal studies, they present sample size formulas to account for within-subject correlation among repeated measurements and various

missing data patterns. For multiple levels of clustering, the level at which to perform randomization actually becomes a design parameter. The authors show how this can greatly impact trial administration, analysis, and sample size requirement. Addressing the overarching theme of sample size determination for correlated outcomes, this book provides a useful resource for biostatisticians, clinical investigators, epidemiologists, and social scientists whose research involves trials with correlated outcomes. Each chapter is self-contained so readers can explore topics relevant to their research projects without having to refer to other chapters.

Sample Size Calculations in Clinical Research - Shein-Chung Chow 2017

Like the well-regarded and bestselling second edition, Sample Size Calculations in Clinical Research, Third Edition, presents statistical procedures for performing sample size calculations during various phases of clinical research and development. This new edition contains updates and four new chapters written specifically for this version.

Innovative Methods for Rare Disease Drug Development - Shein-Chung Chow 2020-11-11

In the United States, a rare disease is defined by the Orphan Drug Act as a disorder or condition that affects fewer than 200,000 persons. For the approval of "orphan" drug products for rare diseases, the traditional approach of power analysis for sample size calculation is not feasible because there are only limited number of subjects available for clinical trials. In this case, innovative approaches are needed for providing substantial evidence meeting the same standards for statistical assurance as drugs used to treat common conditions. Innovative Methods for Rare Disease Drug Development focuses on biostatistical applications in terms of design and analysis in pharmaceutical research and development from both regulatory and scientific (statistical) perspectives. Key Features: Reviews critical issues (e.g., endpoint/margin selection, sample size requirements, and complex innovative design). Provides better understanding of statistical concepts and methods which may be used in regulatory review and approval. Clarifies controversial statistical issues in regulatory review and approval accurately and reliably. Makes recommendations to evaluate rare diseases regulatory submissions. Proposes innovative study designs and statistical methods for rare diseases drug development, including n-of-1 trial design, adaptive trial design, and master protocols like platform trials. Provides insight regarding current regulatory guidance on rare diseases drug development like gene therapy.

Innovative Statistics in Regulatory Science - Shein-Chung Chow 2019-11-14

Statistical methods that are commonly used in the review and approval process of regulatory submissions are usually referred to as statistics in regulatory science or regulatory statistics. In a broader sense, statistics in regulatory science can be defined as valid statistics that are employed in the review and approval process of regulatory submissions of pharmaceutical products. In addition, statistics in regulatory science are involved with the development of regulatory policy, guidance, and regulatory critical clinical initiatives related research. This book is devoted to the discussion of statistics in regulatory science for pharmaceutical development. It covers practical issues that are commonly encountered in regulatory science of pharmaceutical research and development including topics related to research activities, review of regulatory submissions, recent critical clinical initiatives, and policy/guidance development in regulatory science. Devoted entirely to discussing statistics in regulatory science for pharmaceutical development. Reviews critical issues (e.g., endpoint/margin selection and complex innovative design such as adaptive trial design) in the pharmaceutical development and regulatory approval process. Clarifies controversial statistical issues (e.g., hypothesis testing versus confidence interval approach, missing data/estimands, multiplicity, and Bayesian design and approach) in review/approval of regulatory submissions. Proposes innovative thinking regarding study designs and statistical methods (e.g., n-of-1 trial design, adaptive trial design, and probability monitoring procedure for sample size) for rare disease drug development. Provides insight regarding current regulatory clinical initiatives (e.g., precision/personalized medicine, biomarker-driven target clinical trials, model informed drug development, big data analytics, and real world data/evidence). This book provides key statistical concepts, innovative designs, and analysis methods that are useful in regulatory science. Also included are some practical, challenging, and controversial issues that are commonly seen in the review and approval process of regulatory submissions. About the author Shein-Chung Chow, Ph.D. is currently a Professor at Duke University School of Medicine, Durham, NC. He was previously the Associate Director at the Office of Biostatistics, Center for Drug Evaluation and Research, United States Food and Drug Administration (FDA). Dr. Chow has also held various positions in the pharmaceutical industry such as Vice President at Millennium, Cambridge, MA, Executive Director at Covance, Princeton, NJ, and Director and Department Head at Bristol-Myers Squibb, Plainsboro, NJ. He was elected Fellow of the American Statistical Association and an elected member of the ISI (International Statistical Institute). Dr. Chow is Editor-in-Chief of the Journal of Biopharmaceutical Statistics and Biostatistics Book Series, Chapman and Hall/CRC Press, Taylor & Francis, New York. Dr. Chow is the author or co-author of over 300 methodology papers and 30 books.

Adaptive Design Methods in Clinical Trials, Second Edition - Shein-Chung Chow 2011-12-01

With new statistical and scientific issues arising in adaptive clinical trial design, including the U.S. FDA’s recent draft guidance, a new edition of one of the first books on the topic is needed. Adaptive Design Methods in Clinical Trials, Second Edition reflects recent developments and regulatory positions on the use of adaptive designs in clinical trials. It unifies the vast and continuously growing literature and research activities on regulatory

requirements, scientific and practical issues, and statistical methodology. New to the Second Edition Along with revisions throughout the text, this edition significantly updates the chapters on protocol amendment and clinical trial simulation to incorporate the latest changes. It also includes five entirely new chapters on two-stage adaptive design, biomarker adaptive trials, target clinical trials, sample size and power estimation, and regulatory perspectives. Following in the tradition of its acclaimed predecessor, this second edition continues to offer an up-to-date resource for clinical scientists and researchers in academia, regulatory agencies, and the pharmaceutical industry. Written in an intuitive style at a basic mathematical and statistical level, the book maintains its practical approach with an emphasis on concepts via numerous examples and illustrations.

The Essentials of Biostatistics for Physicians, Nurses, and Clinicians - Michael R. Chernick 2011-08-04

A fundamental and straightforward guide to using and understanding statistical concepts in medical research Designed specifically for healthcare practitioners who need to understand basic biostatistics but do not have much time to spare, The Essentials of Biostatistics for Physicians, Nurses and Clinicians presents important statistical methods used in today's biomedical research and provides insight on their appropriate application. Rather than provide detailed mathematics for each of these methods, the book emphasizes what healthcare practitioners need to know to interpret and incorporate the latest biomedical research into their practices. The author draws from his own experience developing and teaching biostatistics courses for physicians and nurses, offering a presentation that is non-technical and accessible. The book begins with a basic introduction to the relationship between biostatistics and medical research, asking the question "why study statistics?," while also exploring the significance of statisitcal methods in medical literature and clinical trials research. Subsequent chapters explore key topics, including: Correlation, regression, and logistic regression Diagnostics Estimating means and proportions Normal distribution and the central limit theorem Sampling from populations Contingency tables Meta-analysis Nonparametric methods Survival analysis Throughout the book, statistical methods that are often utilized in biomedical research are outlined, including repeated measures analysis of variance, hazard ratios, contingency tables, log rank tests, bioequivalence, cross-over designs, selection bias, and group sequential methods. Exercise sets at the end of each chapter allow readers to test their comprehension of the presented concepts and techniques. The Essentials of Biostatistics for Physicians, Nurses, and Clinicians is an excellent reference for doctors, nurses, and other practicing clinicians in the fields of medicine, public health, pharmacy, and the life sciences who need to understand and apply statistical methods in their everyday work. It also serves as a suitable supplement for courses on biostatistics at the upper-undergraduate and graduate levels.

Bayesian Modeling in Bioinformatics - Dipak K. Dey 2010-09-03

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 Statistics from A to Z - B. S. Everitt 2006-12-21

From 'Abcissa' to 'Zygosity determination' - this accessible introduction to the terminology of medical statistics describes more than 1500 terms all clearly explained, illustrated and defined in non-technical language, without any mathematical formulae! With the majority of terms revised and updated and the addition of more than 100 brand new definitions, this new edition will enable medical students to quickly grasp the meaning of any of the statistical terms they encounter when reading the medical literature. Furthermore, annotated comments are used judiciously to warn the unwary of some of the common pitfalls that accompany some cherished biomedical statistical techniques. Wherever possible, the definitions are supplemented with a reference to further reading where the reader may gain a deeper insight, so whilst the definitions are easily disgestible, they also provide a stepping stone to a more sophisticated comprehension. Statistical terminology can be quite bewildering for clinicians: this guide will be a lifesaver.

Adaptive Design Theory and Implementation Using SAS and R - Mark Chang 2014-12-01

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.

Analytical Similarity Assessment in Biosimilar Product Development - Shein-Chung Chow 2018-09-03

This book focuses on analytical similarity assessment in biosimilar product development following the FDA's recommended stepwise approach for obtaining totality-of-the-evidence for approval of biosimilar products. It covers concepts such as the tiered approach for assessment of similarity of critical quality attributes in the manufacturing process of biosimilar products, models/methods like the statistical model for classification of critical quality attributes, equivalence tests for critical quality attributes in Tier 1 and the corresponding sample size requirements, current issues, and recent developments in analytical similarity assessment.

Design and Analysis of Bioavailability and Bioequivalence Studies - Shein-Chung Chow 2008-10-15

Preeminent Experts Update a Well-Respected BookTaking into account the regulatory and scientific developments that have occurred since the second edition, Design and Analysis of Bioavailability and Bioequivalence Studies, Third Edition provides a complete presentation of the latest progress of activities and results in bioavailability and bioequiva

Design and Analysis of Clinical Trials with Time-to-Event Endpoints - Karl E. Peace 2009-04-23

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.

Sample Size Calculations - Paul Mathews 2010

Sample Size Calculations: Practical Methods for Engineers and Scientists presents power and sample size calculations for common statistical analyses including methods for means, standard deviations, proportions, counts, regression, correlation, and measures of agreement. Topics of special interest to quality engineering professionals include designed experiments, reliability studies, statistical process control, acceptance sampling, process capability analysis, statistical tolerancing, and gage error studies. The book emphasizes approximate methods, but exact methods are presented when the approximate methods fail. Monte Carlo and bootstrap methods are introduced for situations that don't satisfy the assumptions of the analytical methods. Solutions are presented for more than 170 example problems and solutions for selected example problems using PASS, MINITAB, Piface, and R are posted on the Internet.

Bayesian Adaptive Methods for Clinical Trials - Scott M. Berry 2010-07-19

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.

The Prevention and Treatment of Missing Data in Clinical Trials - National Research Council 2011-01-21

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.

Dose Finding in Drug Development - Naitee Ting 2006-12-29

If you have ever wondered when visiting the pharmacy how the dosage of your prescription is determined this book will answer your questions. Dosing information on drug labels is based on discussion between the pharmaceutical manufacturer and the drug regulatory agency, and the label is a summary of results obtained from many scientific experiments. The book introduces the drug development process, the design and the analysis of clinical trials. Many of the discussions are based on applications of statistical methods in the design and analysis of dose response studies. Important procedural steps from a pharmaceutical industry perspective are also examined.

Sample Size Calculations for Clustered and Longitudinal Outcomes in Clinical Research - Chul Ahn 2014-12-09

Accurate sample size calculation ensures that clinical studies have adequate power to detect clinically meaningful effects. This results in the efficient use of resources and avoids exposing a disproportionate number of patients to experimental treatments caused by an overpowered study. Sample Size Calculations for Clustered and Longitudinal Outcom

Encyclopedia of Biopharmaceutical Statistics – Four Volume Set - Shein-Chung Chow 2018-09-03

Since the publication of the first edition in 2000, there has been an explosive growth of literature in biopharmaceutical research and development of new medicines. This encyclopedia (1) provides a comprehensive and unified presentation of designs and analyses used at different stages of the drug development process, (2) gives a well-balanced summary of current regulatory requirements, and (3) describes recently developed statistical methods in the pharmaceutical sciences. Features of the Fourth Edition: 1. 78 new and revised entries have been added for a total of 308 chapters and a fourth volume has been added to encompass the increased number of chapters. 2. Revised and updated entries reflect changes and recent developments in regulatory requirements for the drug review/approval process and statistical designs and methodologies. 3. Additional topics include multiple-stage adaptive trial design in clinical research, translational medicine, design and analysis of biosimilar drug development, big data analytics, and real world evidence for clinical research and development. 4. A table of contents organized by stages of biopharmaceutical development provides easy access to relevant topics. About the Editor: Shein-Chung Chow, Ph.D. is currently an Associate Director, Office of Biostatistics, U.S. Food and Drug Administration (FDA). Dr. Chow is an Adjunct Professor at Duke University School of Medicine, as well as Adjunct Professor at Duke-NUS, Singapore and North Carolina State University. Dr. Chow is the Editor-in-Chief of the Journal of Biopharmaceutical Statistics and the Chapman & Hall/CRC Biostatistics Book Series and the author of 28 books and over 300 methodology papers. He was elected Fellow of the American Statistical Association in 1995.

Innovative Methods for Rare Disease Drug Development - Shein-Chung Chow 2020-11-12

In the United States, a rare disease is defined by the Orphan Drug Act as a disorder or condition that affects fewer than 200,000 persons. For the approval of "orphan" drug products for rare diseases, the traditional approach of power analysis for sample size calculation is not feasible because there are only limited number of subjects available for clinical trials. In this case, innovative approaches are needed for providing substantial evidence meeting the same standards for statistical assurance as drugs used to treat common conditions. Innovative Methods for Rare Disease Drug Development focuses on biostatistical applications in terms of design and analysis in pharmaceutical research and development from both regulatory and scientific (statistical) perspectives. Key Features: Reviews critical issues (e.g., endpoint/margin selection, sample size requirements, and complex innovative design). Provides better understanding of statistical concepts and methods which may be used in regulatory review and approval. Clarifies controversial statistical issues in regulatory review and approval accurately and reliably. Makes recommendations to evaluate rare diseases regulatory submissions. Proposes innovative study designs and statistical methods for rare diseases drug development, including n-of-1 trial design, adaptive trial design, and master protocols like platform trials. Provides insight regarding current regulatory guidance on rare diseases drug development like gene therapy.

Linear Regression Analysis - Xin Yan 2009

"This volume presents in detail the fundamental theories of linear regression analysis and diagnosis, as well as the relevant statistical computing techniques so that readers are able to actually model the data using the techniques described in the book. This book is suitable for

graduate students who are either majoring in statistics/biostatistics or using linear regression analysis substantially in their subject area." --Book Jacket.

Statistical Methods for Rates and Proportions - Joseph L. Fleiss 1981-04-21

An introduction to applied probability; Assessing significance in a fourfold table; Determining sample sizes needed to detect a difference between two proportions; How to randomize; Sampling method; The analysis of data from matched samples; The comparison of proportions from several independent samples; Combining evidence from fourfold tables; The effects of misclassification errors; The control of misclassification error; The measurement of interrater agreement; The standardization of rates.

Sample Size Calculations in Clinical Research - Shein-Chung Chow 2003-03-04

Sample size calculation plays an important role in clinical research. It is not uncommon, however, to observe discrepancies among study objectives (or hypotheses), study design, statistical analysis (or test statistic), and sample size calculation. Focusing on sample size calculation for studies conducted during the various phases of clinical research and development, Sample Size Calculation in Clinical Research explores the causes of discrepancies and how to avoid them. This volume provides formulas and procedures for determination of sample size required not only for testing equality, but also for testing non-inferiority/superiority, and equivalence (similarity) based on both untransformed (raw) data and log-transformed data under a parallel-group design or a crossover design with equal or unequal ratio of treatment allocations. It contains a comprehensive and unified presentation of statistical procedures for sample size calculation that are commonly employed at various phases of clinical development. Each chapter includes, whenever possible, real examples of clinical studies from therapeutic areas such as cardiovascular, central nervous system, anti-infective, oncology, and women's health to demonstrate the clinical and statistical concepts, interpretations, and their relationships and interactions. The book highlights statistical procedures for sample size calculation and justification that are commonly employed in clinical research and development. It provides clear, illustrated explanations of how the derived formulas and/or statistical procedures can be used.

Multiple Testing Problems in Pharmaceutical Statistics - Alex Dmitrienko 2009-12-08

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

Bayesian Methods for Measures of Agreement - Lyle D. Broemeling 2009-01-12

Using WinBUGS to implement Bayesian inferences of estimation and testing hypotheses, Bayesian Methods for Measures of Agreement presents useful methods for the design and analysis of agreement studies. It focuses on agreement among the various players in the diagnostic process. The author employs a Bayesian approach to provide statistical inferences based on various models of intra- and interrater agreement. He presents many examples that illustrate the Bayesian mode of reasoning and explains elements of a Bayesian application, including prior information, experimental information, the likelihood function, posterior distribution, and predictive distribution. The appendices provide the necessary theoretical foundation to understand Bayesian methods as well as introduce the fundamentals of programming and executing the WinBUGS software. Taking a Bayesian approach to inference, this hands-on book explores numerous measures of agreement, including the Kappa coefficient, the G coefficient, and intraclass correlation. With examples throughout and end-of-chapter exercises, it discusses how to successfully design and analyze an agreement study.

Encyclopedia of Biopharmaceutical Statistics, Third Edition - Shein-Chung Chow 2010-05-20

In recent years, there has been an explosive growth of biopharmaceutical and clinical research, including the development of new medicines for treating severe or life-threatening diseases. Biopharmaceutical statistics plays an extremely important role in ensuring not only the efficacy and safety of the medicine under investigation, but also that the pharmaceutical product possesses good drug characteristics, such as identity, strength, purity, quality, stability, and reproducibility. Widely used by pharmaceutical scientists, clinical researchers, and biostatistics, the Encyclopedia of Biopharmaceutical Statistics, Third Edition is an essential resource on the evolving state of this important field. New to the Third Edition 89 new chapters, bringing the total number of chapters to 230 Updated information on changes in regulatory requirements for drug review/approval processes Recent developments in statistical design and methodology Important topics, including adaptive design in clinical research, translational medicine, statistical genetics, biomarker development, target clinical trials, follow-on biologics, and traditional Chinese medicine

Statistical Design, Monitoring, and Analysis of Clinical Trials - Weichung Joe Shih 2021-10-26

Statistical Design, Monitoring, and Analysis of Clinical Trials, Second Edition concentrates on the biostatistics component of clinical trials. This new edition is updated throughout and includes five new chapters. Developed from the authors' courses taught to public health and medical students, residents, and fellows during the past 20 years, the text shows how biostatistics in clinical trials is an integration of many fundamental scientific principles and statistical methods. The book begins with ethical and safety principles, core trial design concepts, the principles and methods of sample size and power calculation, and analysis of covariance

and stratified analysis. It then focuses on sequential designs and methods for two-stage Phase II cancer trials to Phase III group sequential trials, covering monitoring safety, futility, and efficacy. The authors also discuss the development of sample size reestimation and adaptive group sequential procedures, phase 2/3 seamless design and trials with predictive biomarkers, exploit multiple testing procedures, and explain the concept of estimand, intercurrent events, and different missing data processes, and describe how to analyze incomplete data by proper multiple imputations. This text reflects the academic research, commercial development, and public health aspects of clinical trials. It gives students and practitioners a multidisciplinary understanding of the concepts and techniques involved in designing, monitoring, and analyzing various types of trials. The book's balanced set of homework assignments and in-class exercises are appropriate for students and researchers in (bio)statistics, epidemiology, medicine, pharmacy, and public health.

Controversial Statistical Issues in Clinical Trials - Shein-Chung Chow 2016-04-19

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.

Sample Size Calculations in Clinical Research - Shein-Chung Chow 2017-08-15

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.

Data and Safety Monitoring Committees in Clinical Trials - Jay Herson 2009-03-13

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.

Sample Size Determination and Power - Thomas P. Ryan 2013-05-28

A comprehensive approach to sample size determination and power with applications for a variety of fields Sample Size Determination and Power features a modern introduction to the applicability of sample size determination and provides a variety of discussions on broad topics including epidemiology, microarrays, survival analysis and reliability, design of experiments, regression, and confidence intervals. The book distinctively merges applications from numerous fields such as statistics, biostatistics, the health sciences, and engineering in order to provide a complete introduction to the general statistical use of sample size determination. Advanced topics including multivariate analysis, clinical trials, and quality improvement are addressed, and in addition, the book provides

considerable guidance on available software for sample size determination. Written by a well-known author who has extensively class-tested the material, Sample Size Determination and Power: Highlights the applicability of sample size determination and provides extensive literature coverage Presents a modern, general approach to relevant software to guide sample size determination including CATD (computer-aided trial design) Addresses the use of sample size determination in grant proposals and provides up-to-date references for grant investigators An appealing reference book for scientific researchers in a variety of fields, such as statistics, biostatistics, the health sciences, mathematics, ecology, and geology, who use sampling and estimation methods in their work, Sample Size Determination and Power is also an ideal supplementary text for upper-level undergraduate and graduate-level courses in statistical sampling.

Bayesian Missing Data Problems - Ming T. Tan 2009-08-26

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.

Sample Sizes for Clinical Trials - Steven A. Julious 2009-08-26

Drawing on various real-world applications, Sample Sizes for Clinical Trials takes readers through the process of calculating sample sizes for many types of clinical trials. It provides descriptions of the calculations with a practical emphasis. Focusing on normal, binary, ordinal, and survival data, the book explores a range of trials, including superiority, equivalence, non-inferiority, bioequivalence, and precision for both parallel group and crossover designs. The author discusses how trial objectives impact the study design with respect to the derivation of formulae for sample size calculations. He uses real-life studies throughout to show how the concepts and calculations can be employed. This work underscores the importance of sample size calculation in the design of a clinical trial. With useful calculation tables throughout, it enables readers to quickly find an appropriate formula, formula application, and associated worked example. Watch the author speak about this book at JSM 2012 in San Diego.

Design and Analysis of Clinical Trials - Shein-Chung Chow 2013-09-30

Praise for the Second Edition: **"**...a grand feast for biostatisticians. It stands readyto satisfy the appetite of any pharmaceutical scientist with arespectable statistical appetite.**"** —Journal of ClinicalResearch Best Practices The Third Edition of Design and Analysis of ClinicalTrials provides complete, comprehensive, and expanded coverageof recent health treatments and interventions. Featuring a unifiedpresentation, the book provides a well-balanced summary of currentregulatory requirements and recently developed statistical methodsas well as an overview of the various designs and analyses that areutilized at different stages of clinical research and development.Additional features of this Third Edition include: • New chapters on biomarker development and targetclinical trials, adaptive design, trials for evaluating diagnosticdevices, statistical methods for translational medicine, andtraditional Chinese medicine • A balanced overview of current and emerging clinicalissues as well as newly developed statistical methodologies • Practical examples of clinical trials that demonstrateeveryday applicability, with illustrations and examples to explainkey concepts • New sections on bridging studies and global trials, QTstudies, multinational trials, comparative effectiveness trials,and the analysis of QT/QTc prolongation • A complete and balanced presentation of clinical andscientific issues, statistical concepts, and methodologies forbridging clinical and statistical disciplines • An update of each chapter that reflects changes inregulatory requirements for the drug review and approval processand recent developments in statistical design and methodology forclinical research and development Design and Analysis of Clinical Trials, Third Editioncontinues to be an ideal clinical research reference for academic,pharmaceutical, medical, and regulatory scientists/researchers,statisticians, and graduate-level students.

Frailty Models in Survival Analysis - Andreas Wienke 2010-07-26

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.

Clinical Trial Methodology - Karl E. Peace 2010-07-20

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.

Quantitative Methods for HIV/AIDS Research - Cliburn Chan 2017-08-07

Quantitative Methods in HIV/AIDS Research provides a comprehensive discussion of modern statistical approaches for the analysis of HIV/AIDS data. The first section focuses on statistical issues in clinical trials and epidemiology that are unique to or particularly challenging in HIV/AIDS research; the second section focuses on the analysis of laboratory data used for immune monitoring, biomarker discovery and vaccine development; the final section focuses on statistical issues in the mathematical modeling of HIV/AIDS pathogenesis, treatment and epidemiology. This book brings together a broad perspective of new quantitative methods in HIV/AIDS research, contributed by statisticians and mathematicians immersed in HIV research, many of whom are current or previous leaders of CFAR quantitative cores. It is the editors' hope that the work will inspire more statisticians, mathematicians and computer scientists to collaborate and contribute to the interdisciplinary challenges of understanding and addressing the AIDS pandemic.