Encyclopedia Of Biopharmaceutical Statistics Third Edition Chow Encyclopedia Of Biopharmaceutical Statistics

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Basic Statistics and Pharmaceutical Statistical Applications, Third Edition - James E. De Muth 2014-04-28
Building on its best-selling predecessors, Basic Statistics and Pharmaceutical Statistical Applications, Third Edition covers statistical topics most relevant to those in the pharmaceutical industry and pharmacy practice. It focuses on the fundamentals required to understand descriptive and inferential statistics for problem solving. Incorporating new material in virtually every chapter, this third edition now provides information on software applications to assist with evaluating data. New to the Third Edition Use of Excel® and Minitab® for performing statistical analysis Discussions of nonprobability sampling procedures, determining if data is normally distributed, evaluation of covariances, and testing for precision equivalence Expanded sections on regression analysis, chi square tests, tests for trends with ordinal data, and tests related to survival statistics Additional nonparametric procedures, including the one-sided sign test, Wilcoxon signed-ranks test, and Mood's median test With the help of flow charts and tables, the author dispels some of the anxiety associated with using basic statistical tests in the pharmacy profession and helps readers correctly interpret their results using statistical software. Through the text's worked-out examples, readers better understand how the mathematics works, the logic behind many of the equations, and the tests' outcomes.
Design and Analysis of Cross-Over Trials, Third Edition - Byron Jones 2014-10-08
Design and Analysis of Cross-Over Trials is concerned with a specific kind of comparative trial known as the cross-over trial, in which subjects receive different sequences of treatments. Such trials are widely used in clinical and medical research, and in other diverse areas such as veterinary science, psychology, sports science, and agriculture. The first edition of this book was the first to be wholly devoted to the subject. The second edition was revised to mirror growth and development in areas where the design remained in widespread use and new areas where it had grown in importance. This new Third Edition: Contains seven new chapters written in the form of short case studies that address re-estimating sample size when testing for average bioequivalence, fitting a nonlinear dose response function, estimating a dose to take forward from phase two to phase three, establishing proof of concept, and recalculating the sample size using conditional power Employs the R package Crossover, specially created to accompany the book and provide a graphical user interface for locating designs in a large catalog and for searching for new designs Includes updates regarding the use of period baselines and the analysis of data from very small trials Reflects the availability of new procedures in SAS, particularly proc glimmix Presents the SAS procedure proc mcmc as an alternative to WinBUGS for Bayesian analysis Complete with real data and downloadable SAS code, Design and Analysis of Cross-Over Trials, Third Edition provides a practical understanding of the latest methods along with the necessary tools for implementation.
Encyclopedia of Chemical Processing (Online) - Sunggyu Lee 2005-11-01
This second edition Encyclopedia supplies nearly 350 gold standard articles on the methods, practices, products, and standards influencing the chemical industries. It offers expertly written articles on technologies at the forefront of the field to maximize and enhance the research and production phases of current and emerging chemical manufacturing practices and techniques. This collecting of information is of vital interest to chemical, polymer, electrical, mechanical, and civil engineers, as well as chemists and chemical researchers. A complete reconceptualization of the classic reference series the Encyclopedia of Chemical Processing and Design, whose first volume published in 1976, this resource offers extensive A-Z treatment of the subject in five simultaneously published volumes, with comprehensive indexing of all five volumes in the back matter of each tome. It includes material on the design of key unit operations involved with chemical processes; the design, unit operation, and integration of reactors and separation systems; process system peripherals such as pumps, valves, and controllers; analytical techniques and equipment; and pilot plant design and scale-up criteria. This reference contains well-researched sections on automation, equipment, design and simulation, reliability and maintenance, separations technologies, and energy and environmental issues. Authoritative contributions cover chemical processing equipment, engineered systems, and laboratory apparatus currently utilized in the field. It also presents expert overviews on key engineering science topics in property predictions, measurements and analysis, novel materials and devices, and emerging chemical fields. ALSO AVAILABLE ONLINE This Taylor & Francis encyclopedia is also available through online subscription, offering a variety of extra benefits for both researchers, students, and librarians, including: Citation tracking and alerts Active reference linking Saved searches and marked lists HTML and PDF format options Contact Taylor and Francis for more information or to inquire about subscription options and print/online combination packages. US: (Tel) 1.888.318.2367; (E-mail) e-reference@taylorandfrancis.com International: (Tel) +44 (0) 20 7017 6062; (E-mail) online.sales@tandf.co.uk
Cancer Clinical Trials - Stephen L. George 2016-08-19
Cancer Clinical Trials: Current and Controversial Issues in Design and Analysis provides statisticians with an understanding of the critical challenges currently encountered in oncology trials. Well-known statisticians from academic institutions, regulatory and government agencies (such as the U.S. FDA and National Cancer Institute), and the pharmaceutical industry share their extensive experiences in cancer clinical trials and present examples taken from actual trials. The book covers topics that are often perplexing and sometimes controversial in cancer clinical trials. Most of the issues addressed are also important for clinical trials in other settings. After discussing general topics, the book focuses on aspects of early and late phase clinical trials. It also explores personalized medicine, including biomarker-based clinical trials, adaptive clinical trial designs, and dynamic treatment regimes.
Biopharmaceutical Applied Statistics Symposium - Karl E. Peace 2018-09-03
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 third of the 3-volume book series. The topics covered include: Targeted Learning of Optimal Individualized Treatment Rules under Cost Constraints, Uses of Mixture Normal

Distribution in Genomics and Otherwise, Personalized Medicine – Design Considerations, Adaptive Biomarker Subpopulation and Tumor Type Selection in Phase III Oncology Trials, High Dimensional Data in Genomics; Synergy or Additivity - The Importance of Defining the Primary Endpoint, Full Bayesian Adaptive Dose Finding Using Toxicity Probability Interval (TPI), Alpha-recycling for the Analyses of Primary and Secondary Endpoints of Clinical Trials, Expanded Interpretations of Results of Carcinogenicity Studies of Pharmaceuticals, Randomized Clinical Trials for Orphan Drug Development, Mediation Modeling in Randomized Trials with Non-normal Outcome Variables, Statistical Considerations in Using Images in Clinical Trials, Interesting Applications over 30 Years of Consulting, Uncovering Fraud, Misconduct and Other Data Quality Issues in Clinical Trials, Development and Evaluation of High Dimensional Prognostic Models, and Design and Analysis of Biosimilar Studies.

Basic Statistics and Pharmaceutical Statistical Applications, Second Edition - James E. De Muth 2006-05-10

The first edition of Basic Statistics and Pharmaceutical Statistical Applications successfully provided a practical, easy-to-read, basic statistics book. This second edition not only updates the previous edition, but expands coverage in the area of biostatistics and how it relates to real-world professional practice. Taking you on a roller coaster ride through the world of statistics, Dr. De Muth clearly details the methodology necessary to summarize data and make informed decisions about observed outcomes. What's new or different in the Second Edition? New chapters cover: Measures of association primarily with nominal and ordinal data and and more than 15 tests Survival statistics including actuarial analysis and an introduction to multiple regression with survival data using proportional hazards regression An introduction to the topic of evidence-based practice with discussions of sensitivity and specificity, predictive values, and likelihood ratios Odds ratios and relative risk ratios that provide valuable information for dealing with probability, odds, and risk New sections address Power and sample size determination for two-sample Z-tests of proportions Clinical equivalence and noninferiority studies, process capability, and tolerance limits Methods for assessing repeatability and reproducibility Expanded information includes: Chi square, repeated measures designs, Latin Square designs, nine multiple comparison tests, and outlier testing Inverse prediction with linear regression, handling of multiple data points at different levels of independent variable, and assessment of parallelism of slopes for two samples Additional types of bivariate correlations and various assessments for independence and randomness More nonparametric tests including new information on post hoc comparisons for a significant Kruskal-Wallis test, the Kolmogorov-Smirnov goodness-of-fit test, and the Anderson-Darling test, as well as runs and range tests Eight new tables useful for the interpretation of some of the new inferential statistics De Muth provides concrete examples that enable you to effectively manage information in your day-to-day problem solving and reporting of findings. By avoiding heavy-duty mathematics and theory, even the mathematically challenged can benefit and increase their confidence in using statistics procedures.

Statistical Topics in Health Economics and Outcomes Research - Demissie Alemayehu, PhD 2017-11-22

With ever-rising healthcare costs, evidence generation through Health Economics and Outcomes Research (HEOR) plays an increasingly important role in decision-making about the allocation of resources. Accordingly, it is now customary for health technology assessment and reimbursement agencies to request for HEOR evidence, in addition to data from clinical trials, to inform decisions about patient access to new treatment options. While there is a great deal of literature on HEOR, there is a need for a volume that presents a coherent and unified review of the major issues that arise in application, especially from a statistical perspective. Statistical Topics in Health Economics and Outcomes Research fulfils that need by presenting an overview of the key analytical issues and best practice. Special attention is paid to key assumptions and other salient features of statistical methods customarily used in the area, and appropriate and relatively comprehensive references are made to emerging trends. The content of the book is purposefully designed to be accessible to readers with basic quantitative backgrounds, while providing an in-depth coverage of relatively complex statistical issues. The book will make a very useful reference for researchers in the pharmaceutical industry, academia, and research institutions involved with HEOR studies. The targeted readers may include statisticians, data scientists, epidemiologists, outcomes researchers, health economists, and healthcare policy and decision-makers.

Encyclopedia of Biopharmaceutical Statistics, Second Edition - Shein-Chung Chow 2003-06-04

The only encyclopedia that specifically focuses on biopharmaceutical statistics, the 3rd Edition provides a well-balanced summary of current regulatory requirements, along with a comprehensive and unified presentation of designs and analyses used at different stages of biopharmaceutical and clinical research and development. This is the definitive statistical guide for the entire pipeline of drug/pharmaceutical product development: from non-clinical and pre-clinical assessments and manufacturing processes through to clinical trials, regulatory processes and postmarketing surveillence. Thoroughly exploring emerging technologies, concepts, and trends, this edition incorporates 89 brand new chapters on subjects such as biomarker development, target clinical trials and follow-on biologics. Previous contents of this title have been revised and updated, and cover topics ranging from in vitro bioequivalence testing and dissolution profile comparison to bridging studies, MedDRA, vaccine clinical trials and medical devices. The encyclopedia also includes popular topics that are currently under discussion within regulatory agencies and the pharmaceutical/biotech industry, such as pharmacoeconomics, reproducibility and probability in clinical research. Available in hard copy and online formats, this highly specialised book is a must-have resource for pharmaceutical R&D departments as well as for statisticians and researchers who work on clinical trials regulated by the FDA.

OECD Series on Testing and Assessment Guidance Document 116 on the Conduct and Design of Chronic Toxicity and Carcinogenicity Studies, Supporting Test Guidelines 451, 452 and 453 Second edition - OECD 2014-09-03

This guidance provides additional information on the conduct of studies performed using Test Guidelines 451, 452 and Test Guideline 453.

Encyclopedia of Natural Resources - Land - Volume I - Yeqiao Wang 2014-07-23

With unprecedented attention on global change, the current debate revolves around the availability and sustainability of natural resources and how to achieve equilibrium between what society demands from natural environments and what the natural resource base can provide. A full understanding of the range of issues, from the consequences of the changing resource bases to the degradation of ecological integrity and the sustainability of life, is crucial to the process of developing solutions to this complex challenge. Authored by world-class scientists and scholars, The Encyclopedia of Natural Resources provides an authoritative reference on a broad spectrum of topics such as the forcing factors and habitats of life; their histories, current status, and future trends; and their societal connections, economic values, and management. The content presents state-of-the-art science and technology development and perspectives of resource management. Written and designed with a broad audience in mind, the entries clearly elucidate the issues for readers at all levels without sacrificing the scientific rigor required by professionals in the field. Volume I – Land includes 98 entries that cover the topical areas of renewable and nonrenewable natural resources such as forest and vegetative; soil; terrestrial coastal and inland wetlands; landscape structure and function and change; biological diversity; ecosystem services, protected areas, and management; natural resource economics; and resource security and sustainability. Natural resources represent such a broad scope of complex and challenging topics that a reference book must cover a vast number of subjects in order to be titled an encyclopedia. The Encyclopedia of Natural Resources does just that. The topics covered help you face current and future issues in the maintenance of clean air and water as well as the preservation of land resources and native biodiversity. Also Available Online This Taylor & Francis encyclopedia is also available through online subscription, offering a variety of extra benefits for researchers, students, and librarians, including: Citation tracking and alerts Active reference linking Saved searches and marked lists HTML and PDF format options Contact Taylor and Francis for more information or to inquire about subscription options and print/online combination packages. US: (Tel) 1.888.318.2367; (E-mail) e-reference@taylorandfrancis.com International: (Tel) +44 (0) 20 7017 6062; (E-mail) online.sales@tandf.co.uk

Encyclopedia of Environmental Management, Four Volume Set - Sven Erik Jorgensen 2012-12-13

Winner of an Outstanding Academic Title Award from CHOICE Magazine Encyclopedia of Environmental Management gives a comprehensive overview of environmental problems, their sources, their assessment, and their solutions. Through in-depth entries and a topical table of

contents, readers will quickly find answers to questions about specific pollution and management issues. Edited by the esteemed Sven Erik Jørgensen and an advisory board of renowned specialists, this four-volume set shares insights from more than 500 contributors—all experts in their fields. The encyclopedia provides basic knowledge for an integrated and ecologically sound management system. Nearly 400 alphabetical entries cover everything from air, soil, and water pollution to agriculture, energy, global pollution, toxic substances, and general pollution problems. Using a topical table of contents, readers can also search for entries according to the type of problem and the methodology. This allows readers to see the overall picture at a glance and find answers to the core questions: What is the pollution problem, and what are its sources? What is the "big picture," or what background knowledge do we need? How can we diagnose the problem, both qualitatively and quantitatively, using monitoring and ecological models, indicators, and services? How can we solve the problem with environmental technology, ecotechnology, cleaner technology, and environmental legislation? How do we address the problem as part of an integrated management strategy? This accessible encyclopedia examines the entire spectrum of tools available for environmental management. An indispensable resource, it guides environmental managers to find the best possible solutions to the myriad pollution problems they face. Also Available Online This Taylor & Francis encyclopedia is also available through online subscription, offering a variety of extra benefits for researchers, students, and librarians, including: Citation tracking and alerts Active reference linking Saved searches and marked lists HTML and PDF format options Contact us to inquire about subscription options and print/online combination packages. US: (Tel) 1.888.318.2367 / (email) e-reference@taylorandfrancis.com International: (Tel) +44 (0) 20 7017 6062 / (email) online.sales@tandf.co.uk

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.

Downstream Industrial Biotechnology - Michael C. Flickinger 2013-07-17

DOWNSTREAM INDUSTRIAL BIOTECHNOLOGY An affordable, easily accessible desk reference on biomanufacturing, focused on downstream recovery and purification Advances in the fundamental knowledge surrounding biotechnology, novel materials, and advanced engineering approaches continue to be translated into bioprocesses that bring new products to market at a significantly faster pace than most other industries. Industrial scale biotechnology and new manufacturing methods are revolutionizing medicine, environmental monitoring and remediation, consumer products, food production, agriculture, and forestry, and continue to be a major area of research. The downstream stage in industrial biotechnology refers to recovery, isolation, and purification of the microbial products from cell debris, processing medium and contaminating biomolecules from the upstream process into a finished product such as biopharmaceuticals and vaccines. Downstream process design has the greatest impact on overall biomanufacturing cost because not only does the biochemistry of different products (e.g., peptides, proteins, hormones, antibiotics, and complex antigens) dictate different methods for the isolation and purification of these products, but contaminating byproducts can also reduce overall process yield, and may have serious consequences on clinical safety and efficacy. Therefore downstream separation scientists and engineers are continually seeking to eliminate, or combine, unit operations to minimize the number of process steps in order to maximize product recovery at a specified concentration and purity. Based on Wiley's Encyclopedia of Industrial Biotechnology: Bioprocess, Bioseparation, and Cell Technology, this volume features fifty articles that provide information on down- stream recovery of cells and protein capture; process development and facility design; equipment; PAT in downstream processes; downstream cGMP operations; and regulatory compliance. It covers: Cell wall disruption and lysis Cell recovery by centrifugation and filtration Large-scale protein chromatography Scale down of biopharmaceutical purification operations Lipopolysaccharide removal Porous media in biotechnology Equipment used in industrial protein purification Affinity chromatography Antibody purification, monoclonal and polyclonal Protein aggregation, precipitation and crystallization Freeze-drying of biopharmaceuticals Biopharmaceutical facility design and validation Pharmaceutical bioburden testing Regulatory requirements Ideal for graduate and advanced undergraduate courses on biomanufacturing, biochemical engineering, biopharmaceutical facility design, biochemistry, industrial microbiology, gene expression technology, and cell culture technology, Downstream Industrial Biotechnology is also a highly recommended resource for industry professionals and libraries.

Introductory Biostatistics for the Health Sciences - Michael R. Chernick 2003-06-24

Accessible to medicine- and/or public policy-related audiences, aswell as most statisticians. Emphasis on outliers is discussed by way of detection andtreatment. Resampling statistics software is incorporated throughout. Motivating applications are presented in light of honesttheory. Plentiful exercises are sprinkled throughout.

Encyclopedia of Public Administration and Public Policy - 5 Volume Set - Domonic A. Bearfield 2020-08-14

Now in its third edition, Encyclopedia of Public Administration and Public Policy remains the definitive source for article-length presentations spanning the fields of public administration and public policy. It includes entries for: Budgeting Bureaucracy Conflict resolution Countries and regions Court administration Gender issues Health care Human resource management Law Local government Methods Organization Performance Policy areas Policy-making process Procurement State government Theories This revamped five-volume edition is a reconceptualization of the first edition by Jack Rabin. It incorporates over 225 new entries and over 100 revisions, including a range of contributions and updates from the renowned academic and practitioner leaders of today as well as the next generation of top scholars. The entries address topics in clear and coherent language and include references to additional sources for further study.

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.

Multiple Comparisons and Multiple Tests Using SAS, Second Edition - Peter H. Westfall 2011

New and extensively updated for SAS 9 and later, this work provides cutting-edge methods, specialized macros, and proven best bet procedures. The book also discusses the pitfalls and advantages of various methods, thereby helping readers to decide which is the most appropriate for their purposes. 644 pp. Pub. 7/11.

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.

Patient-Reported Outcomes - Joseph C. Cappelleri 2013-12-20

Advancing the development, validation, and use of patient-reported outcome (PRO) measures, Patient-Reported Outcomes: Measurement, Implementation and Interpretation helps readers develop and enrich their understanding of PRO methodology, particularly from a quantitative perspective. Designed for biopharmaceutical researchers and others in the health sciences community, it provides an up-to-date volume on conceptual and analytical issues of PRO measures. The book discusses key concepts relating to the measurement, implementation, and interpretation of PRO measures. It covers both introductory and advanced psychometric and biostatistical methods for constructing and analyzing PRO measures. The authors include many relevant real-life applications based on their extensive first-hand experiences in the pharmaceutical industry. They implement a wealth of simulated datasets to illustrate concepts and heighten understanding based on practical scenarios. For readers interested in conducting statistical analyses of PRO measures and delving more deeply into the analytic details, most chapters contain SAS code and output that illustrate the methodology. Along with providing numerous references, the book highlights current regulatory guidelines.

Encyclopedia of Information Systems and Technology - Two Volume Set - Phillip A. Laplante 2015-12-29

Spanning the multi-disciplinary scope of information technology, the Encyclopedia of Information Systems and Technology draws together comprehensive coverage of the inter-related aspects of information systems and technology. The topics covered in this encyclopedia encompass internationally recognized bodies of knowledge, including those of The IT BOK, the Chartered Information Technology Professionals Program, the International IT Professional Practice Program (British Computer Society), the Core Body of Knowledge for IT Professionals (Australian Computer Society), the International Computer Driving License Foundation (European Computer Driving License Foundation), and the Guide to the Software Engineering Body of Knowledge. Using the universally recognized definitions of IT and information systems from these recognized bodies of knowledge, the encyclopedia brings together the information that students, practicing professionals, researchers, and academicians need to keep their knowledge up to date. Also Available Online This Taylor & Francis encyclopedia is also available through online subscription, offering a variety of extra benefits for researchers, students, and librarians, including: □ Citation tracking and alerts □ Active reference linking □ Saved searches and marked lists □ HTML and PDF format options Contact Taylor and Francis for more information or to inquire about subscription options and print/online combination packages. US: (Tel) 1.888.318.2367; (E-mail) e-reference@taylorandfrancis.com International: (Tel) +44 (0) 20 7017 6062; (E-mail) online.sales@tandf.co.uk

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.

Applied Statistics in Biomedicine and Clinical Trials Design - Zhen Chen 2015-05-04

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.

Analysis of Mixed Data - Alexander R. de Leon 2013-01-16

A comprehensive source on mixed data analysis, Analysis of Mixed Data: Methods & Applications summarizes the fundamental developments in the field. Case studies are used extensively throughout the book to illustrate interesting applications from economics, medicine and health, marketing, and genetics. Carefully edited for smooth readability and seamless transitions between chapters All chapters follow a common structure, with an introduction and a concluding summary, and include illustrative examples from real-life case studies in developmental toxicology, economics, medicine and health, marketing, and genetics An introductory chapter provides a "wide angle" introductory overview and comprehensive survey of mixed data analysis Blending theory and methodology, this book illustrates concepts via data from different

disciplines. Analysis of Mixed Data: Methods & Applications traces important developments, collates basic results, presents terminology and methodologies, and gives an overview of statistical research applications. It is a valuable resource to methodologically interested as well as subject matter-motivated researchers in many disciplines.

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.

Encyclopedia of Chemical Processing - Sunggyu Lee 2006

Collecting information of vital interest to chemical, polymer, mechanical, electrical, and civil engineers, as well as chemists and chemical researchers, this "Encyclopedia "supplies nearly 350 articles on current design, engineering, science, and manufacturing practices-offering expertly written articles on technologies at the forefront of the field to maximize and enhance the research and production phases of current and emerging chemical manufacturing practices and techniques.

Pharmaceutical Product Development - Vandana B. Patravale 2016-05-25

Pharmaceutical product development is a multidisciplinary activity involving extensive efforts in systematic product development and optimization in compliance with regulatory authorities to ensure the quality, efficacy and safety of resulting products. Pharmaceutical Product Development equips the pharmaceutical formulation scientist with extensive and up-to-date knowledge of drug product development and covers all steps from the beginning of product conception to the final packaged form that enters the market and lifecycle management thereof. Applications of core scientific principles for product development are also thoroughly discussed in conjunction with the latest approaches involving design of experiment and quality by design with comprehensive illustrations based on practical case studies of several dosage forms. The book presents pharmaceutical product development information in an easy-to-read mode with simplified theories, case studies and guidelines for students, academicians and professionals in the pharmaceutical industry. It is an invaluable resource and hands-on guide covering managerial, regulatory and practical aspects of pharmaceutical product lifecycle management.

Encyclopedia of Optical and Photonic Engineering (Print) - Five Volume Set - Craig Hoffman 2015-09-22

The first edition of the Encyclopedia of Optical and Photonic Engineering provided a valuable reference concerning devices or systems that generate, transmit, measure, or detect light, and to a lesser degree, the basic interaction of light and matter. This Second Edition not only reflects the changes in optical and photonic engineering that have occurred since the first edition was published, but also: Boasts a wealth of new material, expanding the encyclopedia's length by 25 percent Contains extensive updates, with significant revisions made throughout the text Features contributions from engineers and scientists leading the fields of optics and photonics today With the addition of a second editor, the Encyclopedia of Optical and Photonic Engineering, Second Edition offers a balanced and up-to-date look at the fundamentals of a diverse portfolio of technologies and discoveries in areas ranging from x-ray optics to photon entanglement and beyond. This edition's release corresponds nicely with the United Nations General Assembly's declaration of 2015 as the International Year of Light, working in tandem to raise awareness about light's important role in the modern world. Also Available Online This Taylor & Francis encyclopedia is also available through online subscription, offering a variety of extra benefits for researchers, students, and librarians, including: Citation tracking and alerts Active reference linking Saved searches and marked lists HTML and PDF format options Contact Taylor and Francis for more information or to inquire about subscription options and print/online combination packages. US: (Tel) 1.888.318.2367; (E-mail) e-reference@taylorandfrancis.com International: (Tel) +44 (0) 20 7017 6062; (E-mail) online.sales@tandf.co.uk

Noninferiority Testing in Clinical Trials - Tie-Hua Ng 2014-12-01

Take Your NI Trial to the Next LevelReflecting the vast research on noninferiority (NI) designs from the past 15 years, Noninferiority Testing in Clinical Trials: Issues and Challenges explains how to choose the NI margin as a small fraction of the therapeutic effect of the active control in a clinical trial. Requiring no prior knowledge of NI test

Encyclopedia of Natural Resources - Water and Air - Vol II - Yeqiao Wang 2014-07-23

With unprecedented attention on global change, the current debate revolves around the availability and sustainability of natural resources and how to achieve equilibrium between what society demands from natural environments and what the natural resource base can provide. A full understanding of the range of issues, from the consequences of the changing resource bases to the degradation of ecological integrity and the sustainability of life, is crucial to the process of developing solutions to this complex challenge. Authored by world-class scientists and scholars, The Encyclopedia of Natural Resources provides an authoritative reference on a broad spectrum of topics such as the forcing factors and habitats of life; their histories, current status, and future trends; and their societal connections, economic values, and management. The content presents state-of-the-art science and technology development and perspectives of resource management. Written and designed with a broad audience in mind, the entries clearly elucidate the issues for readers at all levels. In Volume II, Water includes 59 entries and Air includes 31 entries. The Water entries cover topical areas such as fresh water, groundwater, water quality and watersheds, ice and snow, coastal environments, and marine resources and economics. The Air entries cover air pollutants, atmospheric oscillation, circulation patterns and atmospheric water storage, as well as agroclimatology, climate change, and extreme events. Additional topics in meteorology include acid rain, drought, ozone depletion, water storage, and more. Natural resources represent such a broad scope of complex and challenging topics that a reference book must cover a vast number of subjects in order to be titled an encyclopedia. The Encyclopedia of Natural Resources does just that. The topics covered help readers face current and future issues in the maintenance of clean air and water as well as the preservation of land resources and native biodiversity. Also Available Online This Taylor & Francis encyclopedia is also available through online subscription, offering a variety of extra benefits for researchers, students, and librarians, including: Citation tracking and alerts Active reference linking Saved searches and marked lists HTML and PDF format options Contact Taylor and Francis for more information or to inquire about subscription options and print/online combination packages. US: (Tel) 1.888.318.2367; (E-mail) e-reference@taylorandfrancis.com International: (Tel) +44 (0) 20 7017 6062; (E-mail) online.sales@tandf.co.uk

Encyclopedia of Soil Science - Rattan Lal 2006

"Upholding the high standard of quality set by the previous edition, this two-volume second edition offers a vast array of recent peer-reviewed articles. It showcases research and practices with added sections on ISTIC-World Soil Information, root growth and agricultural management, nitrate leaching management, podzols, paramos soils, water repellant soils, rare earth elements, and more. With hundreds of entries covering tillage, irrigation, erosion control, ground water, and soil degradation, the book offers quick access to all branches of soil science, from mineralology and physics, to soil management, restoration, and global warming."--Publisher's website.

Clinical Trials in Neurology - Bernard Ravina 2012-04-12

Comprehensive book that suggests ways to improve the efficiency of

clinical trials and the development of interventions in the neurosciences.

Encyclopedia of Natural Resources - Two-Volume Set - Yeqiao Wang 2014-06-01

With unprecedented attention on global change, the current debate revolves around the availability and sustainability of natural resources and how to achieve equilibrium between what society demands from natural environments and what the natural resource base can provide. A full understanding of the range of issues, from the consequences of the changing resource bases to the degradation of ecological integrity and the sustainability of life, is crucial to the process of developing solutions to this complex challenge. Authored by world-class scientists and scholars, The Encyclopedia of Natural Resources provides an authoritative reference on a broad spectrum of topics such as the forcing factors and habitats of life; their histories, current status, and future trends; and their societal connections, economic values, and management. The content presents state-of-the-art science and technology development and perspectives of resource management. Written and designed with a broad audience in mind, the entries clearly elucidate the issues for readers at all levels. Volume I – Land includes 98 entries that cover the topical areas of renewable and nonrenewable natural resources such as forest and vegetative; soil; terrestrial coastal and inland wetlands; landscape structure and function and change; biological diversity; ecosystem services, protected areas, and management; natural resource economics; and resource security and sustainability. In Volume II, Water includes 59 entries and Air includes 31 entries. The Water entries cover topical areas such as fresh water, groundwater, water quality and watersheds, ice and snow, coastal environments, and marine resources and economics. The Air entries cover air pollutants, atmospheric oscillation, circulation patterns and atmospheric water storage, as well as agroclimatology, climate change, and extreme events. Additional topics in meteorology include acid rain, drought, ozone depletion, water storage, and more. Natural resources represent such a broad scope of complex and challenging topics that a reference book must cover a vast number of subjects in order to be titled an encyclopedia. The Encyclopedia of Natural Resources does just that. The topics covered help readers face current and future issues in the maintenance of clean air and water as well as the preservation of land resources and native biodiversity.

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

Advanced Medical Statistics (2nd Edition) - Lu Ying 2015-06-29

The book aims to provide both comprehensive reviews of the classical methods and an introduction to new developments in medical statistics. The topics range from meta analysis, clinical trial design, causal inference, personalized medicine to machine learning and next generation sequence analysis. Since the publication of the first edition, there have been tremendous advances in biostatistics and bioinformatics. The new edition tries to cover as many important emerging areas and reflect as much progress as possible. Many distinguished scholars, who greatly advanced their research areas in statistical methodology as well as practical applications, also have revised several chapters with relevant updates and written new ones from scratch.The new edition has been divided into four sections, including, Statistical Methods in Medicine and Epidemiology, Statistical Methods in Clinical Trials, Statistical Genetics, and General Methods. To reflect the rise of modern statistical genetics as one of the most fertile research areas since the publication of the first edition, the brand new section on Statistical Genetics includes entirely new chapters reflecting the state of the art in the field.Although tightly related, all the book chapters are self-contained and can be read independently. The book chapters intend to provide a convenient launch pad for readers interested in learning a specific topic, applying the related statistical methods in their scientific research and seeking the newest references for in-depth research.

Analysis of Clinical Trials Using SAS - Alex Dmitrienko 2017-07-17

Analysis of Clinical Trials Using SAS®: A Practical Guide, Second Edition bridges the gap between modern statistical methodology and real-world clinical trial applications. Tutorial material and step-by-step instructions illustrated with examples from actual trials serve to define relevant statistical approaches, describe their clinical trial applications, and implement the approaches rapidly and efficiently using the power of SAS. Topics reflect the International Conference on Harmonization (ICH) guidelines for the pharmaceutical industry and address important statistical problems encountered in clinical trials. Commonly used methods are covered, including dose-escalation and dose-finding methods that are applied in Phase I and Phase II clinical trials, as well as important trial designs and analysis strategies that are employed in Phase II and Phase III clinical trials, such as multiplicity adjustment, data monitoring, and methods for handling incomplete data. This book also features recommendations from clinical trial experts and a discussion of relevant regulatory guidelines. This new edition includes more examples and case studies, new approaches for addressing statistical problems, and the following new technological updates: SAS procedures used in group sequential trials (PROC SEQDESIGN and PROC SEQTEST) SAS procedures used in repeated measures analysis (PROC GLIMMIX and PROC GEE) macros for implementing a broad range of randomization-based methods in clinical trials, performing complex multiplicity adjustments, and investigating the design and analysis of early phase trials (Phase I dose-escalation trials and Phase II dose-finding trials) Clinical statisticians, research scientists, and graduate students in biostatistics will greatly benefit from the decades of clinical research experience and the ready-to-use SAS macros compiled in this book.

Confidence Intervals for Discrete Data in Clinical Research - Vivek Pradhan 2021-11-15

Confidence Intervals for Discrete Data in Clinical Research is designed as a toolbox for biomedical researchers. Analysis of discrete data is one of the most used yet vexing areas in clinical research. The array of methodologies available in the literature to address the inferential questions for binomial and multinomial data can be a double-edged sword. On the one hand, these methods open a rich avenue of exploration of data; on the other, the wide-ranging and competing methodologies potentially lead to conflicting inferences, adding to researchers' confusion and frustration and also leading to reporting bias. This book addresses the problems that many practitioners experience in choosing and implementing fit for purpose data analysis methods to answer critical inferential questions for binomial and count data. The book is an outgrowth of the authors' collective experience in biomedical research and provides an excellent overview of inferential questions of interest for binomial proportions and rates based on count data, and reviews various solutions to these problems available in the literature. Each chapter discusses the strengths and weaknesses of the methods and suggests practical recommendations. The book's primary focus is on applications in clinical research, and the goal is to provide direct benefit to the users involved in the biomedical field.

Statistics In the Pharmaceutical Industry, 3rd Edition - C. Ralph Buncher 2005-09-28

The growth of the pharmaceutical industry over the past decade is astounding, but the impact of this growth on statistics is somewhat confusing. While software has made analysis easier and more efficient, regulatory bodies now demand deeper and more complex analyses, and pharmacogenetic/genomic studies serve up an entirely new set of challenges. For more than two decades, Statistics in the Pharmaceutical Industry has been the definitive guide to sorting through the challenges in the industry, and this Third Edition continues that tradition. Updated and expanded to reflect the most recent trends and developments in the field, Statistics in the Pharmaceutical Industry, Third Edition presents chapters written by experts from both regulatory agencies and pharmaceutical companies who discuss everything from experimental design to post-marketing studies. This approach sheds light on what regulators consider acceptable methodologies and what methods have proven successful for industrial statisticians. Both new and revised chapters reflect the increasingly global nature of the industry as represented by authors from Japan and Europe, the increasing trend toward non-inferiority/equivalence testing, adaptive design in clinical

trials, global harmonization of regulatory standards, and multiple comparison studies. The book also examines the latest considerations in anti-cancer studies. Statistics in the Pharmaceutical Industry, Third Edition demystifies the approval process by combining regulatory and industrial points of view, making it a must-read for anyone performing statistical analysis at any point in the drug approval process.

Quantitative Methods for Traditional Chinese Medicine Development - Shein-Chung Chow 2015-12-01

A Western-Based Approach to Analyzing TCMs In recent years, many pharmaceutical companies and clinical research organizations have been focusing on the development of traditional Chinese (herbal) medicines (TCMs) as alternatives to treating critical or life-threatening diseases and as pathways to personalized medicine. Quantitative Methods for Traditional Chinese Medicine Development is the first book entirely devoted to the design and analysis of TCM development from a Western perspective, i.e., evidence-based clinical research and development. The book provides not only a comprehensive summary of innovative quantitative methods for developing TCMs but also a useful desk reference for principal investigators involved in personalized medicine. Written by one of the world's most prominent biostatistics researchers, the book connects the pharmaceutical industry, regulatory agencies, and academia. It presents a state-of-the-art examination of the subject for: Scientists and researchers who are engaged in pharmaceutical/clinical research and development of TCMs Those in regulatory agencies who make decisions in the review and approval process of TCM regulatory submissions Biostatisticians who provide statistical support to assess clinical safety and effectiveness of TCMs and related issues regarding quality control and assurance as well as to test for consistency in the manufacturing processes for TCMs This book covers all of the statistical issues encountered at various stages of pharmaceutical/clinical development of a TCM. It explains regulatory requirements; product specifications and standards; and various statistical techniques for evaluation of TCMs, validation of diagnostic procedures, and testing consistency. It also contains an entire chapter of case studies and addresses critical issues in TCM development and FAQs from a regulatory perspective.

Frontiers in Drug Design and Discovery - Atta-ur-Rahman 2011-02-03

"Frontiers in Drug Design and Discovery" is an Ebook series devoted to publishing the latest and the most important advances in drug design and discovery. Eminent scientists write contributions on all areas of rational drug design and drug discovery inclu

Encyclopedia of Iron, Steel, and Their Alloys (Online Version) - George E. Totten 2016-01-06

The first of many important works featured in CRC Press' Metals and Alloys Encyclopedia Collection, the Encyclopedia of Iron, Steel, and Their Alloys covers all the fundamental, theoretical, and application-related aspects of the metallurgical science, engineering, and technology of iron, steel, and their alloys. This Five-Volume Set addresses topics such as extractive metallurgy, powder metallurgy and processing, physical metallurgy, production engineering, corrosion engineering, thermal processing, metalworking, welding, iron- and steelmaking, heat treating, rolling, casting, hot and cold forming, surface finishing and coating, crystallography, metallography, computational metallurgy, metal-matrix composites, intermetallics, nano- and micro-structured metals and alloys, nano- and micro-alloying effects, special steels, and mining. A valuable reference for materials scientists and engineers, chemists, manufacturers, miners, researchers, and students, this must-have encyclopedia: Provides extensive coverage of properties and recommended practices Includes a wealth of helpful charts, nomograms, and figures Contains cross referencing for quick and easy search Each entry is written by a subject-matter expert and reviewed by an international panel of renowned researchers from academia, government, and industry. Also Available Online This Taylor & Francis encyclopedia is also available through online subscription, offering a variety of extra benefits for researchers, students, and librarians, including: Citation tracking and alerts Active reference linking Saved searches and marked lists HTML and PDF format options Contact Taylor and Francis for more information or to inquire about subscription options and print/online combination packages. US: (Tel) 1.888.318.2367; (E-mail) e-reference@taylorandfrancis.com International: (Tel) +44 (0) 20 7017 6062; (E-mail) online.sales@tandf.co.uk