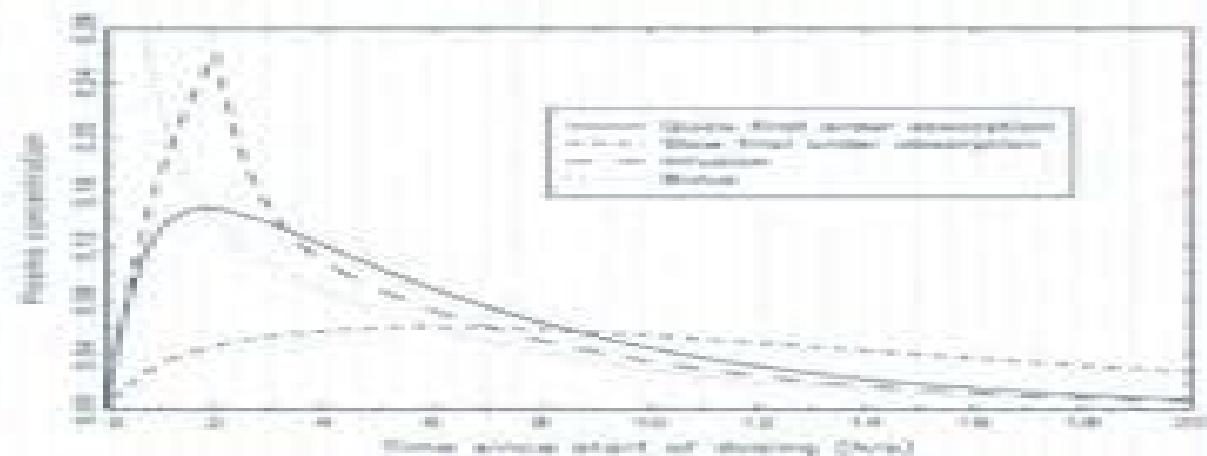




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Biostatistics: A Computing Approach Stewart Anderson, 2011-12-20 The emergence of high speed computing has facilitated the development of many exciting statistical and mathematical methods in the last 25 years, broadening the landscape of available tools in statistical investigations of complex data. *Biostatistics: A Computing Approach* focuses on visualization and computational approaches associated with both mo Clinical and Statistical Considerations in Personalized Medicine Claudio Carini, Sandeep M Menon, Mark Chang, 2014-03-27 *Clinical and Statistical Considerations in Personalized Medicine* explores recent advances related to biomarkers and their translation into clinical development. Leading clinicians, biostatisticians, regulators, commercial professionals, and researchers address the opportunities and challenges in successfully applying biomarkers in drug discovery and preclinical and clinical development. *Robust Biomarkers for Drug Development and Disease Treatment* The first four chapters discuss biomarker development from a clinical perspective. Coverage ranges from an introduction to biomarkers to advances in RNAi, screens, epigenetics, and rare diseases as targets for personalized medicine approaches. Subsequent chapters examine the statistical considerations in applying a personalized medicine approach, including multiplicity in pharmacogenomics. The last chapter assesses the regulatory issues involved in using biomarkers to Improve Patient Care and Reduce Costs and Side Effects. Despite the vast amount of literature on biomarkers, there is no comprehensive book that integrates the clinical and statistical components. This book is one of the first to incorporate both the clinical and statistical aspects of biomarkers in the personalized medicine paradigm. Covering a wide spectrum of personalized medicine related topics, it presents state of the art techniques for advancing the application of biomarkers in drug discovery and development. **Medical Biostatistics, Third Edition** Abhaya Indrayan, 2012-08-07 Encyclopedic in breadth yet practical and concise, *Medical Biostatistics Third Edition* focuses on the statistical aspects of

medicine with a medical perspective showing the utility of biostatistics as a tool to manage many medical uncertainties The author concludes Just as results of medical tests statistical results can be false negative or false positive This edition provides expanded coverage of topics and includes software illustrations The author presents step by step explanations of statistical methods with the help of numerous real world examples Guide charts at the beginning of the book enable quick access to the relevant statistical procedure and the comprehensive index makes it easier to locate terms of interest **Statistical**

Analysis of Human Growth and Development Yin Bun Cheung,2013-10-28 Statistical Analysis of Human Growth and Development is an accessible and practical guide to a wide range of basic and advanced statistical methods that are useful for studying human growth and development Designed for nonstatisticians and statisticians new to the analysis of growth and development data the book collects methods scattered throughout the literature and explains how to use them to solve common research problems It also discusses how well a method addresses a specific scientific question and how to interpret and present the analytic results Stata is used to implement the analyses with Stata codes and macros for generating example data sets a detrended Q Q plot and weighted maximum likelihood estimation of binary items available on the book's CRC Press web page After reviewing research designs and basic statistical tools the author discusses the use of existing tools to transform raw data into analyzable variables and back transform them to raw data He covers regression analysis of quantitative binary and censored data as well as the analysis of repeated measurements and clustered data He also describes the development of new growth references and developmental indices the generation of key variables based on longitudinal data and the processes to verify the validity and reliability of measurement tools Looking at the larger picture of research practice the book concludes with coverage of missing values multiplicity problems and multivariable regression Along with two simulated data sets numerous examples from real experimental and observational studies illustrate the concepts and methods Although the book focuses on examples of anthropometric measurements and changes in cognitive social emotional locomotor and other abilities the ideas are applicable to many other physical and psychosocial phenomena such as lung function and depressive symptoms **Bayesian Analysis Made Simple** Phil Woodward,2016-04-19 Although the popularity of the Bayesian approach to statistics has been growing for years many still think of it as somewhat esoteric not focused on practical issues or generally too difficult to understand Bayesian Analysis Made Simple is aimed at those who wish to apply Bayesian methods but either are not experts or do not have the time to cre

Design and Analysis of Non-Inferiority Trials Mark D. Rothmann,Brian L. Wiens,Ivan S.F. Chan,2016-04-19 The increased use of non inferiority analysis has been accompanied by a proliferation of research on the design and analysis of non inferiority studies Using examples from real clinical trials Design and Analysis of Non Inferiority Trials brings together this body of research and confronts the issues involved in the design of a non inferiority tr

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 cov **Biosimilars** Shein-Chung Chow,2013-07-29 As many biological products face losing their patents in the next decade the pharmaceutical industry needs an abbreviated regulatory pathway for approval of biosimilar drug products which are cost effective follow on subsequent versions of the innovator s biologic products But scientific challenges remain due to the complexity of both the manufacturing process and the structures of biosimilar products Written by a top biostatistics researcher Biosimilars Design and Analysis of Follow on Biologics is the first book entirely devoted to the statistical design and analysis of biosimilarity and interchangeability of biosimilar products It includes comparability tests of important quality attributes at critical stages of the manufacturing processes of biologic products Connecting the pharmaceutical biotechnology industry government regulatory agencies and academia this state of the art book focuses on the scientific factors and practical issues related to the design and analysis of biosimilar studies It covers most of the statistical questions encountered in various study designs at different stages of research and development of biological products

Bayesian Methods in Health Economics Gianluca Baio,2012-11-12 Health economics is concerned with the study of the cost effectiveness of health care interventions This book provides an overview of Bayesian methods for the analysis of health economic data After an introduction to the basic economic concepts and methods of evaluation it presents Bayesian statistics using accessible mathematics The next chapters describe the theory and practice of cost effectiveness analysis from a statistical viewpoint and Bayesian computation notably MCMC The final chapter presents three detailed case studies covering cost effectiveness analyses using individual data from clinical trials evidence synthesis and hierarchical models and Markov models The text uses WinBUGS and JAGS with datasets and code available online

Statistical Evaluation of Diagnostic Performance Kelly H. Zou,Aiyi Liu,Andriy I. Bandos,Lucila Ohno-Machado,Howard E. Rockette,2016-04-19 Statistical evaluation of diagnostic performance in general and Receiver Operating Characteristic ROC analysis in particular are important for assessing the performance of medical tests and statistical classifiers as well as for evaluating predictive models or algorithms This book presents innovative approaches in ROC analysis which are relevant

Advanced Bayesian Methods for Medical Test Accuracy Lyle D. Broemeling,2016-04-19 Useful in many areas of medicine and biology Bayesian methods are particularly attractive tools for the design of clinical trials and diagnostic tests which are based on established information usually from related previous studies Advanced Bayesian Methods for Medical Test Accuracy begins with a review of the usual measures such as specificity

Survival Analysis in Medicine and Genetics Jialiang Li,Shuangge Ma,2013-06-04 Using real data sets throughout Survival Analysis in Medicine and Genetics introduces the latest methods for analyzing high dimensional survival data It provides thorough coverage of recent statistical developments in the medical and genetics fields The text mainly addresses special concerns of the survival model After covering the fundamentals it discusses interval censoring nonparametric and

semiparametric hazard regression multivariate survival data analysis the sub distribution method for competing risks data the cure rate model and Bayesian inference methods The authors then focus on time dependent diagnostic medicine and high dimensional genetic data analysis Many of the methods are illustrated with clinical examples Emphasizing the applications of survival analysis techniques in genetics this book presents a statistical framework for burgeoning research in this area and offers a set of established approaches for statistical analysis It reveals a new way of looking at how predictors are associated with censored survival time and extracts novel statistical genetic methods for censored survival time outcome from the vast amount of research results in genomics Bayesian Modeling in Bioinformatics Dipak K. Dey, Samiran Ghosh, Bani K.

Mallick, 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

Bayesian Methods in Epidemiology Lyle D. Broemeling, 2013-08-13 Written by a biostatistics expert with over 20 years of experience in the field Bayesian Methods in Epidemiology presents statistical methods used in epidemiology from a Bayesian viewpoint It employs the software package WinBUGS to carry out the analyses and offers the code in the text and for download online The book examines study designs that investigate the association between exposure to risk factors and the occurrence of disease It covers introductory adjustment techniques to compare mortality between states and regression methods to study the association between various risk factors and disease including logistic regression simple and multiple linear regression categorical ordinal regression and nonlinear models The text also introduces a Bayesian approach for the estimation of survival by life tables and illustrates other approaches to estimate survival including a parametric model based on the Weibull distribution and the Cox proportional hazards nonparametric model Using Bayesian methods to estimate the lead time of the modality the author explains how to screen for a disease among individuals that do not exhibit any symptoms of the disease With many examples and end of chapter exercises this book is the first to introduce epidemiology from a Bayesian perspective It shows epidemiologists how these Bayesian models and techniques are useful in studying the association between disease and exposure to risk factors Optimal Design for Nonlinear Response Models Valerii V.

Fedorov, Sergei L. Leonov, 2013-07-15 Optimal Design for Nonlinear Response Models discusses the theory and applications of model based experimental design with a strong emphasis on biopharmaceutical studies The book draws on the authors many years of experience in academia and the pharmaceutical industry While the focus is on nonlinear models the book begins with an explanation of Multiple Testing Problems in Pharmaceutical Statistics Alex Dmitrienko, Ajit C.

Tamhane, Frank Bretz, 2009-12-08 Useful Statistical Approaches for Addressing Multiplicity Issues Includes 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 comparison research with an emphasis on pharmaceutical applications. In each chapter the expert contributors describe important multiplicity problems encountered in pre clinical and clinical trial settings. The book begins with a broad introduction from a regulatory perspective to different types of multiplicity problems that commonly arise in confirmatory controlled clinical trials before giving an overview of the concepts, principles and procedures of multiple testing. It then presents statistical methods for analyzing clinical dose response studies that compare several dose levels with a control as well as statistical methods for analyzing multiple endpoints in clinical trials. After covering gatekeeping procedures for testing hierarchically ordered hypotheses, the book discusses statistical approaches for the design and analysis of adaptive designs and related confirmatory hypothesis testing problems. The final chapter focuses on the design of pharmacogenomic studies based on established statistical principles. It also describes the analysis of data collected in these studies taking into account the numerous multiplicity issues that occur. This volume explains how to solve critical issues in multiple testing encountered in pre clinical and clinical trial applications. It presents the necessary statistical methodology along with examples and software code to show how to use the methods in practice.

Design and Analysis of Bridging Studies

Jen-pei Liu, Shein-Chung Chow, Chin-Fu Hsiao, 2012-07-26. As the development of medicines has become more globalized, the geographic variations in the efficacy and safety of pharmaceutical products need to be addressed. To accelerate the product development process and shorten approval time, researchers are beginning to design multiregional trials that incorporate subjects from many countries around the world.

Theory of Drug Development

Eric B. Holmgren, 2013-10-24. Theory of Drug Development presents a formal quantitative framework for understanding drug development that goes beyond simply describing the properties of the statistics in individual studies. It examines the drug development process from the perspectives of drug companies and regulatory agencies. By quantifying various ideas underlying drug development, the book shows how to systematically address problems such as: Sizing a phase 2 trial and choosing the range of p values that will trigger a follow up phase 3 trial; Deciding whether a drug should receive marketing approval based on its phase 2/3 development program and recent experience with other drugs in the same clinical area; Determining the impact of adaptive designs on the quality of drugs that receive marketing approval; Designing a phase 3 pivotal study that permits the data driven adjustment of the treatment effect estimate; Knowing when enough information has been gathered to show that a drug improves the survival time for the whole patient population; Drawing on his extensive work as a statistician in the pharmaceutical industry, the author focuses on the efficient development of drugs and the quantification of evidence in drug development. He provides a rationale for underpowered phase 2 trials based on the notion of efficiency which leads to the identification of an admissible family of phase 2 designs. He also develops a framework for evaluating the strength of evidence generated by clinical trials. This approach is based on the ratio of power to type 1 error and transcends typical Bayesian and frequentist statistical analyses.

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 o

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