

BASIC STATISTICS AND PHARMACEUTICAL STATISTICAL APPLICATIONS

Second Edition



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Scott Evans,Naitee Ting



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Elementary Bayesian Biostatistics Lemuel A. Moyé, 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 explores Statistical Methods for Drug Safety Robert D. Gibbons, Anup Amatya, 2015-07-28 Explore Important Tools for High Quality Work in Pharmaceutical Safety Statistical Methods for Drug Safety presents a wide variety of statistical approaches for analyzing pharmacoepidemiologic data It covers both commonly used techniques such as proportional reporting ratios for the analysis of spontaneous adverse event reports and newer approaches such as the use of marginal structural models for controlling dynamic selection bias in the analysis of large scale longitudinal observational data Choose the Right Statistical Approach for Analyzing Your Drug Safety Data The book describes linear and non linear mixed effects models discrete time survival models and new approaches to the meta analysis of rare binary adverse events It explores research involving the re analysis of complete longitudinal patient records from randomized clinical trials The book discusses causal inference models including propensity score matching marginal structural models and differential effects as well as mixed effects Poisson regression models for analyzing ecological data such as county level adverse event rates The authors also cover numerous other methods useful for the analysis of within subject and between subject variation in adverse events abstracted from large scale medical claims databases electronic health records and additional observational data streams Advance Statistical Practice in Pharmacoepidemiology Authored by two professors at the forefront of developing new statistical methodologies to address pharmacoepidemiologic problems this book provides a cohesive compendium of statistical methods that pharmacoepidemiologists can readily use in their work It also encourages statistical scientists to develop new methods that go beyond the foundation covered in the text *Handbook of Regression and Modeling* Daryl S. Paulson, 2006-12-19 Carefully designed for use by clinical and pharmaceutical researchers and scientists *Handbook of Regression Analysis and Modeling* explores statistical methods that have been adapted into biological applications for the quickly evolving field of biostatistics The author clearly delineates a six step method for hypothesis testing using data that mi Adaptive Design Methods in Clinical Trials Shein-Chung Chow, Mark Chang, 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 clini *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

Quantitative Evaluation of Safety in Drug Development Qi Jiang,H. Amy Xia,2014-12-08 State of the Art Methods for Drug Safety Assessment Responding to the increased scrutiny of drug safety in recent years Quantitative Evaluation of Safety in Drug Development Design Analysis and Reporting explains design monitoring analysis and reporting issues for both clinical trials and observational studies in biopharmaceutical product development It presents the latest statistical methods for drug safety assessment The book s three sections focus on study design safety monitoring and data evaluation analysis The book addresses key challenges across regulatory agencies industry and academia It discusses quantitative approaches to safety evaluation and risk management in drug development covering Bayesian methods effective safety graphics and risk benefit evaluation Written by a team of experienced leaders this book brings the most advanced knowledge and statistical methods of drug safety to the statistical clinical and safety community It shares best practices and stimulates further research and methodology development in the drug safety area

Fundamental Concepts for New Clinical Trialists

Scott Evans,Naitee Ting,2015-11-04 Fundamental Concepts for New Clinical Trialists describes the core scientific concepts of designing data monitoring analyzing and reporting clinical trials as well as the practical aspects of trials not typically discussed in statistical methodology textbooks The first section of the book provides background information about clinical trials I

Multiregional Clinical Trials for Simultaneous Global New Drug Development Joshua Chen,Hui Quan,2016-04-21 In a global clinical development strategy multiregional clinical trials MRCTs are vital in the development of innovative medicines Multiregional Clinical Trials for Simultaneous Global New Drug Development presents a comprehensive overview on the current status of conducting MRCTs in clinical development International experts from academia in

Statistical Methods for Healthcare Performance Monitoring Alex Bottle,Paul Aylin,2016-08-05 Healthcare is important to everyone yet large variations in its quality have been well documented both between and within many countries With demand and expenditure rising it s more crucial than ever to know how well the healthcare system and all its components from staff member to regional network are performing This requires data which inevitably differ in form and quality It also requires statistical methods the output of which needs to be presented so that it can be understood by whoever needs it to make decisions Statistical Methods for Healthcare Performance Monitoring covers measuring quality types of data risk adjustment defining good and bad performance statistical monitoring presenting the results to different audiences and evaluating the monitoring system itself Using examples from around the world it brings all the issues and perspectives together in a largely non technical way for clinicians managers and methodologists Statistical Methods for Healthcare Performance Monitoring is

aimed at statisticians and researchers who need to know how to measure and compare performance health service regulators health service managers with responsibilities for monitoring performance and quality improvement scientists including those involved in clinical audits *Clinical Trial Methodology* Karl E. Peace, Ding-Geng (Din) Chen, 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 wor

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