

Multiple Testing Problems in Pharmaceutical Statistics

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Gerald van Belle



Multiple Testing Problems In Pharmaceutical Statistics Multiple Testing Problems In Pharmaceutical Statistics:

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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

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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 **AMSTAT News** American Statistical Association,2008 **Pharmaceutical Statistics** Sanford Bolton,1990 **Handbook of Multiple Comparisons** Xinping Cui,Thorsten Dickhaus,Ying Ding,Jason C. Hsu,2021-11-17 Written by experts that include originators of some key ideas chapters in the Handbook of Multiple Testing cover multiple comparison problems big and small with guidance toward error rate control and insights on how principles developed earlier can be applied to current and emerging problems Some highlights of the coverages are as follows Error rate control is useful for controlling the incorrect decision rate Chapter 1 introduces Tukey s original multiple comparison error rates and point to how they have been applied and adapted to modern multiple comparison problems as discussed in the later chapters Principles endure While the closed testing principle is more familiar Chapter 4 shows the partitioning principle can derive confidence sets for multiple tests which may become important as the profession goes beyond making decisions based on p values Multiple comparisons of treatment efficacy often involve multiple doses and endpoints Chapter 12 on multiple endpoints explains how different choices of endpoint types lead to different multiplicity adjustment strategies while Chapter 11 on the MCP Mod approach is particularly useful for dose finding To assess efficacy in clinical trials with multiple doses and multiple endpoints the reader can see the traditional approach in Chapter 2 the Graphical approach in Chapter 5 and the multivariate approach in Chapter 3 Personalized precision medicine based on targeted therapies already a reality naturally leads to analysis of efficacy in subgroups Chapter 13 draws attention to subtle logical issues in inferences on subgroups and their mixtures with a principled solution that resolves these issues This chapter has implication toward meeting the ICHE9R1 Estimands requirement Besides the mere multiple testing methodology itself the handbook also covers related topics like the statistical task of model selection in Chapter 7 or the estimation of the proportion of true null hypotheses or in other words the signal prevalence in Chapter 8 It also contains decision theoretic considerations regarding the admissibility of multiple tests in Chapter 6 The issue of selected inference is addressed in Chapter 9 Comparison of responses can involve millions of voxels in medical imaging or SNPs in genome wide association studies GWAS Chapter 14 and Chapter 15 provide state of the art methods for large scale simultaneous inference in these settings **Pharmaceutical Statistics Practical And Clinical Applications, Third Edition** Bolton Sanford,1997-01-17 This edition offers new and expanded information on recent developments in stability data analysis concepts of statistical outliers bioequivalence studies problems in sampling and devising limits for product release covariance analysis and tolerance intervals multiple endpoints and clinical data analysis and more student price which is available upon request from Marcel Dekker **Journal of the American Statistical Association** ,2009 **Journal of Statistical Planning and Inference** North-Holland Publishing Company,2002 **PSAP, Pharmacotherapy Self-assessment Program: Science and practice of pharmacotherapy I, Science and practice of pharmacotherapy**

II American College of Clinical Pharmacy,2002 **Statistical Rules of Thumb Gerald van Belle,2002-03-22** This handbook intends to provide simple rules of thumb widely applicable robust elegant and that capture key statistical concepts It provides a framework for considering statistical questions such as sample size and design of experiments *Wiley Encyclopedia of Clinical Trials* Lisa Marie Sullivan,Joseph Massaro,2008 Here you ll find more than 500 entries from the world s leading experts in the field on the basic concepts methodologies and applications in clinical trials The range of topics includes basic statistical concepts design and analysis of clinical trials ethics regulatory issues and methodologies for clinical data management and analysis **Clinical Trial Biostatistics and Biopharmaceutical Applications** Walter R. Young,Ding-Geng (Din) Chen,2014-11-20 Since 1945 The Annual Deming Conference on Applied Statistics has been an important event in the statistics profession In Clinical Trial Biostatistics and Biopharmaceutical Applications prominent speakers from past Deming conferences present novel biostatistical methodologies in clinical trials as well as up to date biostatistical applications from the pharmaceutical industry Divided into five sections the book begins with emerging issues in clinical trial design and analysis including the roles of modeling and simulation the pros and cons of randomization procedures the design of Phase II dose ranging trials thorough QT QTc clinical trials and assay sensitivity and the constancy assumption in noninferiority trials The second section examines adaptive designs in drug development discusses the consequences of group sequential and adaptive designs and illustrates group sequential design in R The third section focuses on oncology clinical trials covering competing risks escalation with overdose control EWOC dose finding and interval censored time to event data In the fourth section the book describes multiple test problems with applications to adaptive designs graphical approaches to multiple testing the estimation of simultaneous confidence intervals for multiple comparisons and weighted parametric multiple testing methods The final section discusses the statistical analysis of biomarkers from omics technologies biomarker strategies applicable to clinical development and the statistical evaluation of surrogate endpoints This book clarifies important issues when designing and analyzing clinical trials including several misunderstood and unresolved challenges It will help readers choose the right method for their biostatistical application Each chapter is self contained with references Mathematical Statistics with Applications in Biometry Joachim Kunert,Götz Trenkler,2001 Proceedings of the Section on Bayesian Statistical Science American Statistical Association. Section on Bayesian Statistical Science,1994 British Pharmaceutical Codex ,1994 **Brazilian Journal of Probability and Statistics** ,2001 Applied Statistics in Agriculture ,2001 **Current Index to Statistics, Applications, Methods and Theory** ,1999 The Current Index to Statistics CIS is a bibliographic index of publications in statistics probability and related fields **Bayesian Statistics 3** J. M. Bernardo,1988 The field of statistics has undergone rapid and wide development during the past two decades and the Bayesian approach to statistics has provided both a general framework and a creative stimulus for all aspects of this development This volume describes the work presented at the Third Valencia

International Meeting on Bayesian Statistics the main source of information and communication about the current state of knowledge and research in Bayesian statistics throughout the world The research presented which encompasses both invited papers and selected contributed papers has had a profound effect on the foundations of statistical inference and probability statistical theory and methodology and the applications of statistics in science technology medicine business law and public policy The contributors to this volume form a virtual Who's Who in the area of Bayesian statistics Journal of the American Veterinary Medical Association American Veterinary Medical Association, 2015

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