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# **BASIC STATISTICS AND PHARMACEUTICAL STATISTICAL APPLICATIONS**

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**THIRD EDITION**

**James E. De Muth**



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# Basic Statistics And Pharmaceutical Statistical Applications

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Wang, Jun Shao**



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**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

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Data and Safety Monitoring Committees in Clinical Trials Jay

Herson,2009-03-13 Focusing on the practical clinical and statistical issues that arise in pharmaceutical industry trials this book summarizes the author s experience in serving on many data monitoring committees DMCs and in heading up a contract research organization that provided statistical support to nearly seventy five DMCs It explains the difference in DMC operations between the pharmaceutical industry and National Institutes of Health NIH sponsored trials Leading you through the types of reports for adverse events and lab values the author presents the statistical requirements of data monitoring committees and gives advice on how statisticians can best interact with physician members of these committees He also shows how physicians think differently about safety data than statisticians proving that both views are needed

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the trial Drawing from the authors courses on the subject as well as the first author s more than 30 years wor *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 Bayesian Methods for Measures of Agreement Lyle D. Broemeling,2009-01-12 Using WinBUGS to implement Bayesian inferences of estimation and testing hypotheses Bayesian Methods for Measures of Agreement presents useful methods for the design and analysis of agreement studies It focuses on agreement among the various players in the diagnostic process The author employs a Bayesian approach to provide statistical inferences *Elementary Bayesian Biostatistics* Lemuel A. Moye,2016-04-19 Bayesian analyses have made important inroads in modern clinical research due in part to the incorporation of the traditional tools of noninformative priors as well as the modern innovations of adaptive randomization and predictive power Presenting an introductory perspective to modern Bayesian procedures *Elementary Bayesian Biostatistics* explo Medical Biostatistics Abhaya Indrayan,2008-03-10 Emphasizing statistical concepts used in medicine the interpretation of methods and applications *Medical Biostatistics Second Edition* shows how biostatistical methods are important tools in managing uncertainties in medicine and the health sciences With coverage ranging from elementary topics such as mean and standard deviation to adv **Sample Size Calculations in Clinical Research, Second Edition** Shein-Chung Chow,Hansheng Wang,Jun Shao,2007-08-22 Focusing on an integral part of pharmaceutical development *Sample Size Calculations in Clinical Research Second Edition* presents statistical procedures for performing sample size calculations during various phases of clinical research and development It provides sample size formulas and procedures for testing equality noninferiority superiority and equivalence A comprehensive and unified presentation of statistical concepts and practical applications this book highlights the interactions between clinicians and biostatisticians includes a well balanced summary of current and emerging clinical issues and explores recently developed statistical methodologies for sample size calculation Whenever possible each chapter provides a brief history or background regulatory requirements statistical designs and methods for data analysis real world examples future research developments and related references One of the few books to systematically summarize clinical research procedures this edition contains new chapters that focus on three key areas of this field Incorporating the material of this book in your work will help ensure the validity and ultimately the success of your clinical studies **Computational Pharmacokinetics** Anders Kallen,2007-07-19 Being that pharmacokinetics PK is the study of how the body handles various substances it is not surprising that PK plays an important role in the early development of new drugs However the clinical research community widely believes that mathematics in some way blurs the true meaning of PK Demonstrating that quite the opposite is true *Computational Pharmacokinetics* outlines the fundamental concepts and models of PK from a

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