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THIRD EDITION

James E. De Muth



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Basic Statistics And Pharmaceutical Statistical Applications

James E. De Muth



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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 **Bayesian Methods for Measures of Agreement** Lyle D.

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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 mathematical perspective based on clinically relevant parameters After an introductory chapter the book presents a noncompartmental approach to PK and discusses the numerical analysis of PK data including a description of an absorption process through numerical deconvolution The author then builds a simple physiological model to better understand PK volumes and compares this model to other methods The book also introduces compartmental models discusses their limitations and creates a general purpose type of model The final chapter looks at the relationship between drug concentration and effect known as PK pharmacodynamics PD modeling With both a solid discussion of theory and the use of practical examples this book will enable readers to thoroughly grasp the computational factors of PK modeling

Design and Analysis of Bioavailability and Bioequivalence Studies Shein-Chung Chow,Jen-pei Liu,2008-10-15 Preeminent Experts Update a Well Respected BookTaking into account the regulatory and scientific developments that have occurred since the second edition Design and Analysis of Bioavailability and Bioequivalence Studies Third Edition provides a complete presentation of the latest progress of activities and results in bioavailability and bioequiva *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

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