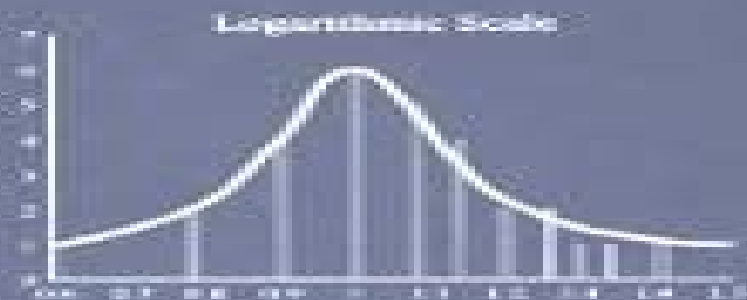
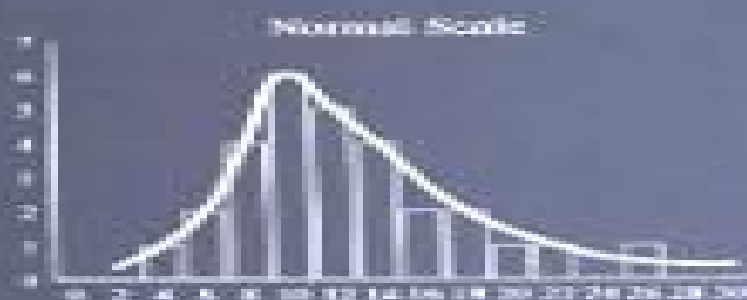


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Data and Safety Monitoring Committees in Clinical Trials Jay Herson, 2009-03-13 Focusing on the practical clinical and statistical issues that arise in pharmaceutical industry trials this book summarizes the author's experience in serving on many data 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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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

Sample Size Calculations in Clinical Research Shein-Chung Chow, Jun Shao, Hansheng Wang, Yuliya Lokhnygina, 2017-08-15 Praise for the Second Edition this is a useful comprehensive compendium of almost every possible sample size formula The strong organization and carefully defined formulae will aid any researcher designing a study Biometrics This impressive book contains formulae for computing sample size in a wide range of settings One sample studies and two sample comparisons for quantitative binary and time to event outcomes are covered comprehensively with separate sample size formulae for testing equality non inferiority and equivalence Many less familiar topics are also covered Journal of the Royal Statistical Society Sample Size Calculations in Clinical Research Third Edition presents statistical procedures for performing sample size calculations during various phases of clinical research and development A comprehensive and unified presentation of statistical concepts and practical applications this book includes a well balanced summary of current and emerging clinical issues regulatory requirements and recently developed statistical methodologies for sample size calculation Features Compares the relative merits and disadvantages of statistical methods for sample size calculations Explains how the formulae and procedures for sample size calculations can be used in a variety of clinical research and development stages Presents real world examples from several therapeutic areas including cardiovascular medicine the central nervous system anti infective medicine oncology and women s health Provides sample size calculations for dose response studies microarray studies and Bayesian approaches This new edition is updated throughout includes many new sections and five new chapters on emerging topics two stage seamless adaptive designs cluster randomized trial design zero inflated Poisson distribution clinical trials with extremely low incidence rates and clinical trial simulation

Computational Methods in Biomedical Research Ravindra Khattree, Dayanand Naik, 2007-12-12 Continuing advances in biomedical research and statistical methods call for a constant stream of updated cohesive accounts of new developments so that the methodologies can be properly implemented in the biomedical field Responding to this need Computational Methods in Biomedical Research explores important current and emerging computational statistical methods that are used in biomedical research Written by active researchers in the field this authoritative collection covers a wide range of topics It introduces each topic at a basic level before moving on to more advanced discussions of applications The book begins with microarray data analysis machine learning techniques and mass spectrometry based protein profiling It then uses state space models to predict US cancer mortality rates and provides an overview of the application of multistate models in analyzing multiple failure times The book also describes various Bayesian techniques the sequential monitoring of randomization tests mixed effects models and the classification rules for repeated measures data The volume concludes with estimation methods for analyzing longitudinal data Supplying the knowledge

necessary to perform sophisticated statistical analyses this reference is a must have for anyone involved in advanced biomedical and pharmaceutical research It will help in the quest to identify potential new drugs for the treatment of a variety of diseases 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

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