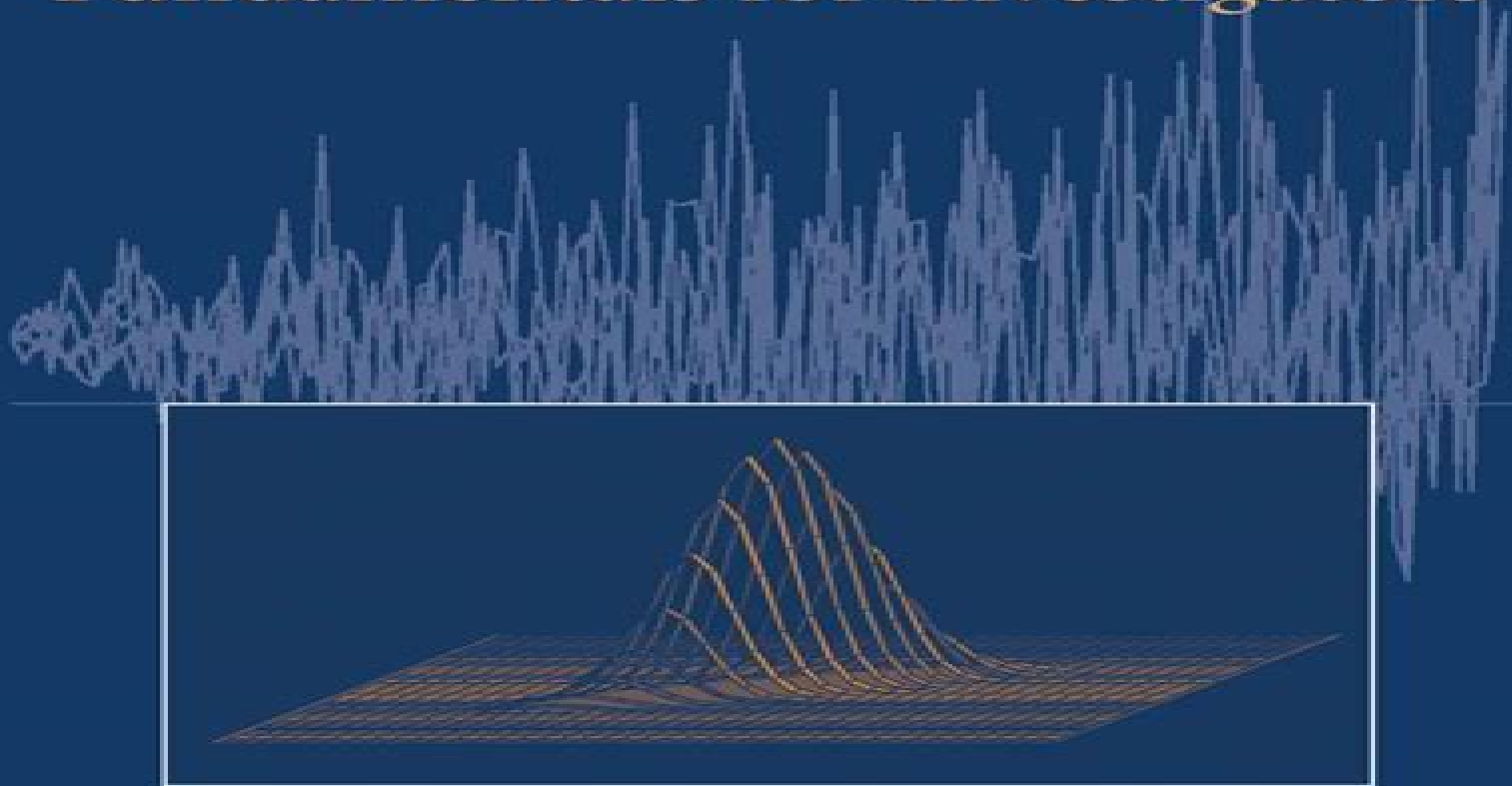


Lemuel A. Moyé

Statistical Monitoring of Clinical Trials

Fundamentals for Investigators



 Springer

Statistical Monitoring Of Clinical Trials Fundamentals For Investigators

Luc Duchateau, Paul Janssen



Statistical Monitoring Of Clinical Trials Fundamentals For Investigators:

Statistical Monitoring of Clinical Trials Lemuel A. Moyé, 2006-02-28 *Statistical Monitoring of Clinical Trials Fundamentals for Investigators* introduces the investigator and statistician to monitoring procedures in clinical research. Clearly presenting the necessary background with limited use of mathematics, this book increases the knowledge, experience, and intuition of investigators in the use of these important procedures now required by the many clinical research efforts. The author provides motivated clinical investigators the background, correct use, and interpretation of these monitoring procedures at an elementary statistical level. He defines terms commonly used such as group sequential procedures and stochastic curtailment in non-mathematical language and discusses the commonly used procedures of Pocock, O'Brien, Fleming, and Lan DeMets. He discusses the notions of conditional power, monitoring for safety and futility, and monitoring multiple endpoints in the study. The use of monitoring clinical trials is introduced in the context of the evolution of clinical research, and one chapter is devoted to the more recent Bayesian procedures. From the reviews: "The author has a wealth of experience in this area and this is demonstrated throughout the text with relevant poignant examples." *Short Book Reviews of the ISI*, June 2006.

Multiple Analyses in Clinical Trials Lemuel A. Moyé, 2003-07-30 Concentrating on the rationale for the analyses, the difficulties posed by their interpretation, easily understood solutions, and useful problem sets, this book will help clinical investigators understand multiple analysis procedures and key issues. It is written for advanced medical students, clinical investigators at all levels, research groups within the pharmaceutical industry, regulators at the local, state, and federal level, and biostatisticians. **Statistical Monitoring of Clinical Trials** Michael A. Proschan, K. K. Gordon, Lan, Janet Turk Wittes, 2006-12-31 The approach taken in this book is to study what the Central Limit Theorem is to studies with only one analysis. Just as the Central Limit Theorem shows that test statistics involving very different types of clinical trial outcomes are asymptotically normal, this book shows that the joint distribution of the test statistics at different analysis times is asymptotically multivariate normal with the correlation structure of Brownian motion. The B value is irrespective of the test statistic. Thus, this book offers statisticians an accessible, incremental approach to understanding Brownian motion as related to clinical trials. *Fundamentals of Clinical Research* Antonella Bacchieri, Giovanni Della Cioppa, 2007-04-29 Here is a new book on methods and issues in clinical research. Its objectives can be summarized in three points: 1. Integrate medical and statistical components of clinical research. 2. Do justice to the operational and practical requirements of clinical research. 3. Give space to the ethical implications of methodological issues in clinical research. The book ends with a brief description of the drug development process and the phases of clinical development. **Principles and Practice of Clinical Research** John I. Gallin, Frederick P. Ognibene, Laura Lee Johnson, 2017-11-17 *Principles and Practice of Clinical Research*, Fourth Edition, has been thoroughly revised to provide a comprehensive look at both the fundamental principles and expanding practice of clinical research. New to this edition of this highly regarded reference

authors have focused on examples that broadly reflect clinical research on a global scale while including a discussion of international regulations studies and implications In addition to key topics such as bioethics clinical outcome data cultural diversity protocol guidelines and omic platforms this edition contains new chapters devoted to electronic health records and information resources for clinical researchers as well as the many opportunities associated with big data Covering a vast number of topics and practical advice for both novice and advanced clinical investigators this book is a highly relevant and essential resource for all those involved in conducting research Features input from experts in the field dedicated to translating scientific research from bench to bedside and back Provides expanded coverage of global clinical research Contains hands on practical suggestions illustrations and examples throughout Includes new chapters on the international regulation of drugs and biologics the emergence of the important role of comparative effectiveness research and how to identify clinical risks and manage patient safety in a clinical research setting

Weighing the Evidence Lem

Moyé,2020-03-09 Clinical research is being strangled Developed in the 1920 s statistical hypothesis testing was accepted into mainstream medical research in the 1950s and served well to provide structure to clinical research However statistical hypothesis testing was not developed specifically for clinical research and has been forced to undergo continuous adaptations in order to maintain relevance Despite this effort it has not kept up with clinical research sophistication that now generates an abundance of analyses Since it has been unable to adapt sufficiently statistical hypothesis testing is stunting the growth of clinical research maintaining its p value dominance at an unacceptable cost The thesis of this book is that clinical research with its need to assess benefit and risk its safety prerogative and its plethora of research designs requires an analysis rubric specifically designed for it This new foundation is based on 1 the concept of duality where a statistical effect size estimate can simultaneously provide evidence for benefit and evidence for harm and 2 the notion that clinical research analyses can be partitioned into regions of analysis that can be weighted through the use of set and measure theory The entire theory is provided from first principles requiring only a rudimentary background in clinical research

Handbook of Integrative Clinical Psychology, Psychiatry, and Behavioral Medicine Roland A. Carlstedt,2009-12-14

This is the long awaited text on interdisciplinary treatment and assessment of among other clinical topics brain derived behavioral cognitive and neurological disorders Niels Birbaumer PhD University of Tübingen Germany Member of the German Academy of Sciences Leopoldina Gone is the unidimensional approach of the expert summarizing a topic from a single vantage point Instead the content shifts laterally embracing not only interdisciplinary expertise but an integrative way of thinking that transcends each discipline What makes the Handbook so refreshing is that this cross pollination of ideas and approaches is more than novel theorizing It offers clinicians a new way forward Anthony Feinstein MD MPhil PhD FRCP University of Toronto To maintain the highest standards allied health care practitioners must keep pace with evolving trends in diagnostics interventions and methodologies This book supports clinicians by disseminating important perspectives research and

procedures It provides an integrative roadmap that fosters interdisciplinary cooperation Key Features Presents reviews of research on a broad selection of clinical disorders Includes a wide range of established and emerging diagnostic and intervention approaches Discusses viable evidence based alternative treatment methods Critiques certain approaches paradigms and practices that may need to be revised Includes contributions from renowned psychologists psychiatrists and researchers Clinicians researchers and students will find this book a valuable source for interdisciplinary practice and research It facilitates a sorely needed move toward integrative practice in an era in which specialization pervades

Encyclopedia of Health Services Research Ross M. Mullner, 2009-05-15 Today as never before healthcare has the ability to enhance the quality and duration of life At the same time healthcare has become so costly that it can easily bankrupt governments and impoverish individuals and families Health services research is a highly multidisciplinary field including such areas as health administration health economics medical sociology medicine political science public health and public policy The Encyclopedia of Health Services Research is the first single reference source to capture the diversity and complexity of the field With more than 400 entries these two volumes investigate the relationship between the factors of cost quality and access to healthcare and their impact upon medical outcomes such as death disability disease discomfort and dissatisfaction with care Key Features Examines the growing healthcare crisis facing the United States Encompasses the structure process and outcomes of healthcare Aims to improve the equity efficiency effectiveness and safety of healthcare by influencing and developing public policies Describes healthcare systems and issues from around the globe Key Themes Access to Care Accreditation Associations Foundations and Research Organizations Biographies of Current and Past Leaders Cost of Care Economics Finance and Payment Mechanisms Disease Disability Health and Health Behavior Government and International Healthcare Organizations Health Insurance Health Professionals and Healthcare Organizations Health Services Research Laws Regulations and Ethics Measurement Data Sources and Coding and Research Methods Outcomes of Care Policy Issues Healthcare Reform and International Comparisons Public Health Quality and Safety of Care Special and Vulnerable Groups The Encyclopedia is designed to be an introduction to the various topics of health services research for an audience including undergraduate students graduate students and general readers seeking non technical descriptions of the field and its practices It is also useful for healthcare practitioners wishing to stay abreast of the changes and updates in the field

The Frailty Model Luc Duchateau, Paul Janssen, 2007-10-23 Clustered survival data are encountered in many scientific disciplines including human and veterinary medicine biology epidemiology public health and demography Frailty models provide a powerful tool to analyse clustered survival data In contrast to the large number of research publications on frailty models relatively few statistical software packages contain frailty models It is demanding for statistical practitioners and graduate students to grasp a good knowledge on frailty models from the existing literature This book provides an in depth discussion and explanation of the basics of frailty model methodology for such readers The discussion includes

parametric and semiparametric frailty models and accelerated failure time models Common techniques to fit frailty models include the EM algorithm penalised likelihood techniques Laplacian integration and Bayesian techniques More advanced frailty models for hierarchical data are also included Real life examples are used to demonstrate how particular frailty models can be fitted and how the results should be interpreted The programs to fit all the worked out examples in the book are available from the Springer website with most of the programs developed in the freeware packages R and Winbugs The book starts with a brief overview of some basic concepts in classical survival analysis collecting what is needed for the reading on the more complex frailty models

The Statistics of Gene Mapping David Siegmund, Benjamin Yakir, 2007-05-27 This book details the statistical concepts used in gene mapping first in the experimental context of crosses of inbred lines and then in outbred populations primarily humans It presents elementary principles of probability and statistics which are implemented by computational tools based on the R programming language to simulate genetic experiments and evaluate statistical analyses Each chapter contains exercises both theoretical and computational some routine and others that are more challenging The R programming language is developed in the text

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