

Jozef Nauta

Statistics in Clinical Vaccine Trials



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Statistics In Clinical Vaccine Trials

M.Elizabeth Halloran,Donald Berry



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Statistics in Clinical and Observational Vaccine Studies Jozef Nauta, 2020-03-14 This book offers an overview of the statistical methods used in clinical and observational vaccine studies Pursuing a practical rather than theoretical approach it presents a range of real world examples with SAS codes making the application of the methods straightforward This revised edition has been significantly expanded to reflect the current interest in this area It opens with two introductory chapters on the immunology of vaccines to provide readers with the necessary background knowledge It then continues with an in depth exploration of the analysis of immunogenicity data Discussed are amongst others maximum likelihood estimation for censored antibody titers ANCOVA for antibody values analysis of data of equivalence and non inferiority immunogenicity studies Other topics covered include fitting protection curves to data from vaccine efficacy studies and the analysis of vaccine safety data In addition the book features four new chapters on vaccine field studies an introductory one one on randomized vaccine efficacy studies one on observational vaccine effectiveness studies and one on the meta analysis of vaccine efficacy studies The book offers useful insights for statisticians and epidemiologists working in the pharmaceutical industry or at vaccines institutes as well as graduate students interested in pharmaceutical statistics

Biostatistics in Clinical Trials Carol K.

Redmond, Theodore Colton, 2001-04-25 The second volume in the Wiley reference series in Biostatistics Featuring articles from the prestigious Encyclopedia of Biostatistics many of which have been fully revised and updated to include recent developments Biostatistics in Clinical Trials also includes up to 25% newly commissioned material reflecting the latest thinking in Bayesian methods Benefit risk assessment Cost effectiveness Ethics Fraud With exceptional contributions from leading experts in academia government and industry Biostatistics in Clinical Trials has been designed to complement existing texts by providing extensive up to date coverage and introducing the reader to the research literature Offering

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Bioequivalence and Statistics in Clinical Pharmacology Scott D. Patterson, Byron Jones, 2017-03-27 Maintaining a practical perspective Bioequivalence and Statistics in Clinical Pharmacology Second Edition explores statistics used in day to day clinical pharmacology work The book is a starting point for those involved in such research and covers the methods needed to design analyze and interpret bioequivalence trials explores when how and why these studies are performed as part of drug development and demonstrates the methods using real world examples Drawing on knowledge gained directly from working in the pharmaceutical industry the authors set the stage by describing the general role of statistics Once the foundation of clinical pharmacology drug development regulatory applications and the design and analysis of bioequivalence trials are established including recent regulatory changes in design and analysis and in particular sample size adaptation they move on to related topics in clinical pharmacology involving the use of cross over designs These include but are not limited to safety studies in Phase I dose response trials drug interaction trials food effect and combination trials QTc and other pharmacodynamic equivalence trials proof of concept trials dose proportionality trials and vaccines trials This second edition addresses several recent developments in the field including new chapters on adaptive bioequivalence studies scaled average bioequivalence testing and vaccine trials Purposefully designed to be instantly applicable Bioequivalence and Statistics in Clinical Pharmacology Second Edition provides examples of SAS and R code so that the analyses described can be immediately implemented The authors have made extensive use of the proc mixed procedures available in SAS

The Prevention and Treatment of Missing Data in Clinical Trials National Research Council, Division of Behavioral and Social Sciences and Education, Committee on National Statistics, Panel on Handling Missing Data in Clinical Trials, 2011-01-21 Randomized clinical trials are the primary tool for evaluating new medical interventions Randomization provides for a fair comparison between treatment and control groups balancing out on average distributions of known and unknown factors among the participants Unfortunately these studies often lack a substantial percentage of data This missing data reduces the benefit provided by the randomization and introduces potential biases in the comparison of the treatment groups Missing data can arise for a variety of reasons including the inability or unwillingness of participants to meet appointments for evaluation And in some studies some or all of data collection ceases when participants discontinue study treatment Existing guidelines for the design and conduct of clinical trials and the analysis of the resulting data provide only limited advice on how to handle

missing data Thus approaches to the analysis of data with an appreciable amount of missing values tend to be ad hoc and variable The Prevention and Treatment of Missing Data in Clinical Trials concludes that a more principled approach to design and analysis in the presence of missing data is both needed and possible Such an approach needs to focus on two critical elements 1 careful design and conduct to limit the amount and impact of missing data and 2 analysis that makes full use of information on all randomized participants and is based on careful attention to the assumptions about the nature of the missing data underlying estimates of treatment effects In addition to the highest priority recommendations the book offers more detailed recommendations on the conduct of clinical trials and techniques for analysis of trial data **Methods and**

Applications of Statistics in Clinical Trials, Volume 2 Narayanaswamy Balakrishnan, 2014-06-09 Methods and Applications of Statistics in Clinical Trials Volume 2 Planning Analysis and Inferential Methods includes updates of established literature from the Wiley Encyclopedia of Clinical Trials as well as original material based on the latest developments in clinical trials Prepared by a leading expert the second volume includes numerous contributions from current prominent experts in the field of medical research In addition the volume features Multiple new articles exploring emerging topics such as evaluation methods with threshold empirical likelihood methods nonparametric ROC analysis over and under dispersed models and multi armed bandit problems Up to date research on the Cox proportional hazard model frailty models trial reports intrarater reliability conditional power and the kappa index Key qualitative issues including cost effectiveness analysis publication bias and regulatory issues which are crucial to the planning and data management of clinical trials

Strategy and Statistics in Clinical Trials Joseph Tal, 2011-07-14 Delineates the statistical building blocks and concepts of clinical trials **Methods and Applications of Statistics in Clinical Trials, Volume 1** Narayanaswamy Balakrishnan, 2014-03-05 A complete guide to the key statistical concepts essential for the design and construction of clinical trials As the newest major resource in the field of medical research Methods and Applications of Statistics in Clinical Trials Volume 1 Concepts Principles Trials and Designs presents a timely and authoritative review of the central statistical concepts used to build clinical trials that obtain the best results The reference unveils modern approaches vital to understanding creating and evaluating data obtained throughout the various stages of clinical trial design and analysis Accessible and comprehensive the first volume in a two part set includes newly written articles as well as established literature from the Wiley Encyclopedia of Clinical Trials Illustrating a variety of statistical concepts and principles such as longitudinal data missing data covariates biased coin randomization repeated measurements and simple randomization the book also provides in depth coverage of the various trial designs found within phase I IV trials Methods and Applications of Statistics in Clinical Trials Volume 1 Concepts Principles Trials and Designs also features Detailed chapters on the type of trial designs such as adaptive crossover group randomized multicenter non inferiority non randomized open labeled preference prevention and superiority trials Over 100 contributions from leading academics researchers and practitioners An exploration of ongoing

cutting edge clinical trials on early cancer and heart disease mother to child human immunodeficiency virus transmission trials and the AIDS Clinical Trials Group Methods and Applications of Statistics in Clinical Trials Volume 1 Concepts Principles Trials and Designs is an excellent reference for researchers practitioners and students in the fields of clinical trials pharmaceuticals biostatistics medical research design biology biomedicine epidemiology and public health **Statistical Methods for Immunogenicity Assessment** Harry Yang, Jianchun Zhang, Binbing Yu, Wei Zhao, 2015-07-17 Develop Effective Immunogenicity Risk Mitigation Strategies Immunogenicity assessment is a prerequisite for the successful development of biopharmaceuticals including safety and efficacy evaluation Using advanced statistical methods in the study design and analysis stages is therefore essential to immunogenicity risk assessment and mitigation strategies *Biostatistics in Biopharmaceutical Research and Development* Ding-Geng Chen, 2024-12-24 The Deming Conference on Applied Statistics has long been deemed an influential event in the biostatistics and biopharmaceutical profession It provides learning experience on recent developments in statistical methodologies in biopharmaceutical applications and FDA regulations This book honors 80 years of contributions and dedication of the Deming Conference in biostatistics and biopharmaceutical clinical trial methodology and applications All chapters are contributed by world class and prominent Deming speakers who have contributed their cutting edge research and developments to the community Volume 2 covers Biomarkers in Drug Development Time To Event Data Analysis and Methods and emerging development in biopharmaceutical biostatistics This book aims to booster research education and training in biostatistics and in biopharmaceutical research and development Advanced Statistical Methods in Life Science Basavarajaiah D.M, Narasimhamurthy B, 2025-07-25 This book introduces the principles and foundations of advanced statistical methods for designing experiments and testing hypotheses in life sciences Advanced statistical methods such as testing of hypotheses recent methods of sample size determination imputation estimation techniques probability distributions and univariate analysis demonstrated with real data and their integration into life sciences are included in this book Advanced topics are presented with sufficient conceptual depth and examples to explain the use of recent statistical techniques and to demonstrate what conclusions can be drawn at the right time using modeling in life science research Key features Explains the derivation of statistical models to prove disease transmission using massive real world datasets to explore practical applicability Incorporates the application of innovative advanced statistical and epidemiological models and demonstrates the possible solutions for public health policy intervention Helps to understand the process of hypothesis testing in small or larger observations by using weighted parameters Presents suitable examples and real life research datasets and all models can easily be followed in formulating statistical and mathematical derivations and key points Includes machine learning ML statistical methods for meta analysis testing of hypotheses methods of imputation estimation techniques probability distributions univariate analysis and recent nonparametric methods all illustrated through actual data This textbook is for students and scholars of various courses in life sciences medicine

mathematics and statistical science It will also help academicians and researchers to understand the foundation of this topic

Encyclopedia of Biopharmaceutical Statistics - Four Volume Set Shein-Chung Chow, 2018-09-03 Since the publication of the first edition in 2000 there has been an explosive growth of literature in biopharmaceutical research and development of new medicines This encyclopedia 1 provides a comprehensive and unified presentation of designs and analyses used at different stages of the drug development process 2 gives a well balanced summary of current regulatory requirements and 3 describes recently developed statistical methods in the pharmaceutical sciences Features of the Fourth Edition 1 78 new and revised entries have been added for a total of 308 chapters and a fourth volume has been added to encompass the increased number of chapters 2 Revised and updated entries reflect changes and recent developments in regulatory requirements for the drug review approval process and statistical designs and methodologies 3 Additional topics include multiple stage adaptive trial design in clinical research translational medicine design and analysis of biosimilar drug development big data analytics and real world evidence for clinical research and development 4 A table of contents organized by stages of biopharmaceutical development provides easy access to relevant topics About the Editor Shein Chung Chow Ph D is currently an Associate Director Office of Biostatistics U S Food and Drug Administration FDA Dr Chow is an Adjunct Professor at Duke University School of Medicine as well as Adjunct Professor at Duke NUS Singapore and North Carolina State University Dr Chow is the Editor in Chief of the Journal of Biopharmaceutical Statistics and the Chapman Hall CRC Biostatistics Book Series and the author of 28 books and over 300 methodology papers He was elected Fellow of the American Statistical Association in 1995

Handbook of Statistics in Clinical Oncology John Crowley, Antje Hoering, Donna Ankerst, 2005-12-01 A compendium of cutting edge statistical approaches to solving problems in clinical oncology Handbook of Statistics in Clinical Oncology Second Edition focuses on clinical trials in phases I II and III proteomic and genomic studies complementary outcomes and exploratory methods Cancer Forum called the first edition a

Fundamentals of Clinical Trials Lawrence M. Friedman, Curt D. Furberg, David L. DeMets, 2010-09-09 The clinical trial is the most definitive tool for evaluation of the applicability of clinical research It represents a key research activity with the potential to improve the quality of health care and control costs through careful comparison of alternative treatments 1 It has been called on many occasions the gold st dard against which all other clinical research is measured Although many clinical trials are of high quality a careful reader of the medical literature will notice that a large number have deficiencies in design conduct analysis presentation and or interpretation of results Improvements have occurred over the past few decades but too many trials are still conducted without adequate attention to its fundamental principles Certainly numerous studies could have been upgraded if the authors had had a better understanding of the fundamentals Since the publication of the first edition of this book a large number of other texts on clinical trials have appeared most of which are indicated here 2 21 Several of them however discuss only specific issues involved in clinical trials Additionally many are no longer current The

purpose of this fourth edition is to update areas in which major progress has been made since the publication of the third edition We have revised most chapters considerably and added one on ethical issues Proceedings of the Fourth Seattle Symposium in Biostatistics: Clinical Trials Thomas R. Fleming, Bruce S. Weir, 2012-12-12 This volume contains a selection of chapters based on papers presented at the Fourth Seattle Symposium in Biostatistics Clinical Trials The symposium was held in 2010 to celebrate the 40th anniversary of the University of Washington School of Public Health and Community Medicine It featured keynote lectures by David DeMets and Susan Ellenberg and 16 invited presentations by other prominent researchers The papers contained in this volume encompass recent methodological advances in several important clinical trials research such as biomarkers meta analyses sequential and adaptive clinical trials and various genetic bioinformatic techniques This volume will be a valuable reference for researchers and practitioners in the field of clinical trials *Applied Statistics in Biomedicine and Clinical Trials Design* Zhen Chen, Aiyi Liu, Yongming Qu, Larry Tang, Naitee Ting, Yi Tsong, 2015-05-04 This volume is a unique combination of papers that cover critical topics in biostatistics from academic government and industry perspectives The 6 sections cover Bayesian methods in biomedical research Diagnostic medicine and classification Innovative Clinical Trials Design Modelling and Data Analysis Personalized Medicine and Statistical Genomics The real world applications are in clinical trials diagnostic medicine and genetics The peer reviewed contributions were solicited and selected from some 400 presentations at the annual meeting of the International Chinese Statistical Association ICSA held with the International Society for Biopharmaceutical Statistics ISBS The conference was held in Bethesda in June 2013 and the material has been subsequently edited and expanded to cover the most recent developments

Clinical Trials in Oncology Stephanie Green, Jacqueline Benedetti, 2012-05-09 The new edition of the bestselling Clinical Trials in Oncology provides a concise nontechnical and now thoroughly up to date review of methods and issues related to clinical trials The authors emphasize the importance of proper study design analysis and data management and identify the pitfalls inherent in these processes This edition includes a new section covering innovations in Phase I designs and another on overcoming the challenges of array data As always the authors use clear lucid prose and a multitude of real world trials as examples to convey the principles of successful trials without the need for a strong statistics or mathematics background

Statistical Models in Epidemiology, the Environment, and Clinical Trials M. Elizabeth Halloran, Donald Berry, 2012-12-06 This IMA Volume in Mathematics and its Applications STATISTICAL MODELS IN EPIDEMIOLOGY THE ENVIRONMENT AND CLINICAL TRIALS is a combined proceedings on Design and Analysis of Clinical Trials and Statistics and Epidemiology Environment and Health This volume is the third series based on the proceedings of a very successful 1997 IMA Summer Program on Statistics in the Health Sciences I would like to thank the organizers M Elizabeth Halloran of Emory University Biostatistics and Donald A Berry of Duke University Institute of Statistics and Decision Sciences and Cancer Center Biostatistics for their excellent work as organizers of the meeting and for editing the proceedings I am grateful to Seymour

Geisser of University of Minnesota Statistics Patricia Grambsch University of Minnesota Biostatistics Joel Greenhouse Carnegie Mellon University Statistics Nicholas Lange Harvard Medical School Brain Imaging Center McLean Hospital Barry Margolin University of North Carolina Chapel Hill Biostatistics Sandy Weisberg University of Minnesota Statistics Scott Zeger Johns Hopkins University Biostatistics and Marvin Zelen Harvard School of Public Health Biostatistics for organizing the six weeks summer program I also take this opportunity to thank the National Science Foundation NSF and the Army Research Office ARO whose financial support made the workshop possible Willard Miller Jr *Sample Sizes for Clinical Trials* Steven A. Julious, 2023-06-21 *Sample Sizes for Clinical Trials* Second Edition is a practical book that assists researchers in their estimation of the sample size for clinical trials Throughout the book there are detailed worked examples to illustrate both how to do the calculations and how to present them to colleagues or in protocols The book also highlights some of the pitfalls in calculations as well as the key steps that lead to the final sample size calculation Features Comprehensive coverage of sample size calculations including Normal binary ordinal and survival outcome data Covers superiority equivalence non inferiority bioequivalence and precision objectives for both parallel group and crossover designs Highlights how trial objectives impact the study design with respect to both the derivation of sample formulae and the size of the study Motivated with examples of real life clinical trials showing how the calculations can be applied New edition is extended with all chapters revised some substantially and four completely new chapters on multiplicity cluster trials pilot studies and single arm trials The book is primarily aimed at researchers and practitioners of clinical trials and biostatistics and could be used to teach a course on sample size calculations The importance of a sample size calculation when designing a clinical trial is highlighted in the book It enables readers to quickly find an appropriate sample size formula with an associated worked example complemented by tables to assist in the calculations

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