

KUNG-JONG LUI

BINARY DATA ANALYSIS OF
**Randomized
Clinical Trials**
WITH NONCOMPLIANCE



WILEY

STATISTICS IN PRACTICE

Binary Data Analysis Of Randomized Clinical Trials With Noncompliance

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Fleming, David L. DeMets**

Binary Data Analysis Of Randomized Clinical Trials With Noncompliance:

Binary Data Analysis of Randomized Clinical Trials with Noncompliance Kung-Jong Lui, 2011-03-31 It is quite common in a randomized clinical trial RCT to encounter patients who do not comply with their assigned treatment. Since noncompliance often occurs non-randomly, the commonly used approaches including both the as-treated AT and as-protocol AP analysis and the intent-to-treat ITT or as-randomized analysis are all well known to possibly produce a biased inference of the treatment efficacy. This book provides a systematic and organized approach to analyzing data for RCTs with noncompliance under the most frequently encountered situations. These include parallel sampling, stratified sampling, cluster sampling, parallel sampling with subsequent missing outcomes, and a series of dependent Bernoulli sampling for repeated measurements. The author provides a comprehensive approach by using contingency tables to illustrate the latent probability structure of observed data. Using real life examples, computer simulated data, and exercises in each chapter, the book illustrates the underlying theory in an accessible and easy to understand way. Key features: Consort flow diagrams and numerical examples are used to illustrate the bias of commonly used approaches such as AT analysis, AP analysis, and ITT analysis for a RCT with noncompliance. Real life examples are used throughout the book to explain the practical usefulness of test procedures and estimators. Each chapter is self-contained, allowing the book to be used as a reference source. Includes SAS programs which can be easily modified in calculating the required sample size. Biostatisticians, clinicians, researchers, and data analysts working in pharmaceutical industries will benefit from this book. This text can also be used as supplemental material for a course focusing on clinical statistics or experimental trials in epidemiology, psychology, and sociology.

Applied Missing Data Analysis in the Health Sciences Xiao-Hua Zhou, Chuan Zhou, Danping Lui, Xaiobo Ding, 2014-05-19 *Applied Missing Data Analysis in the Health Sciences* A modern and practical guide to the essential concepts and ideas for analyzing data with missing observations in the field of biostatistics. With an emphasis on hands-on applications, *Applied Missing Data Analysis in the Health Sciences* outlines the various statistical methods for the analysis of missing data. The authors acknowledge the limitations of established techniques and provide newly developed methods with concrete applications in areas such as causal inference. Organized by types of data, chapter coverage begins with an overall introduction to the existence and limitations of missing data and continues into techniques for missing data inference, including likelihood based, weighted GEE, multiple imputation, and Bayesian methods. The book subsequently covers cross sectional, longitudinal, hierarchical, and survival data. In addition, *Applied Missing Data Analysis in the Health Sciences* features multiple data sets that can be replicated using SAS, Stata, R, and WinBUGS software packages. Numerous examples of case studies to illustrate real world scenarios and demonstrate applications of discussed methodologies. Detailed appendices to guide readers through the use of the presented data in various software environments. *Applied Missing Data Analysis in the Health Sciences* is an excellent textbook for upper undergraduate and graduate level biostatistics courses as well as an ideal resource for health

science researchers and applied statisticians

Behavioral Clinical Trials for Chronic Diseases

Lynda H. Powell, Kenneth E. Freedland, Peter G. Kaufmann, 2021-10-13 This is the first comprehensive guide to the design of behavioral randomized clinical trials RCT for chronic diseases. It includes the scientific foundations for behavioral trial methods problems that have been encountered in past behavioral trials advances in design that have evolved and promising trends and opportunities for the future. The value of this book lies in its potential to foster an ability to speak the language of medicine through the conduct of high quality behavioral clinical trials that match the rigor commonly seen in double blind drug trials. It is relevant for testing any treatment aimed at improving a behavioral social psychosocial environmental or policy level risk factor for a chronic disease including for example obesity sedentary behavior adherence to treatment psychosocial stress food deserts and fragmented care. Outcomes of interest are those that are of clinical significance in the treatment of chronic diseases including standard risk factors such as cholesterol blood pressure and glucose and clinical outcomes such as hospitalizations functional limitations excess morbidity quality of life and mortality. This link between behavior and chronic disease requires innovative clinical trial methods not only from the behavioral sciences but also from medicine epidemiology and biostatistics. This integration does not exist in any current book or in any training program in either the behavioral sciences or medicine.

Data Monitoring Committees in Clinical Trials Susan S. Ellenberg, Thomas R. Fleming, David L. DeMets, 2019-04-01 The authoritative guide for Data Monitoring Committees fully revised and updated. The number of clinical trials sponsored by government agencies and pharmaceutical companies has grown in recent years prompting an increased need for interim monitoring of data on safety and efficacy. Data Monitoring Committees DMCs are an essential component of many clinical trials safeguarding trial participants and protecting the credibility and validity of the study. *Data Monitoring Committees in Clinical Trials A Practical Perspective* 2nd Edition offers practical advice for those managing and conducting clinical trials and serving on Data Monitoring Committees providing a practical overview of the establishment purpose and responsibilities of these committees. Examination of topics such as the composition and independence of DMCs statistical philosophical and ethical considerations and determining when a DMC is needed presents readers with a comprehensive foundational knowledge of clinical trial oversight. Providing recent examples to illustrate DMC principles this fully updated guide reflects current developments and practices in clinical trial oversight and offers expanded coverage of emerging issues and challenges in the field. This new second edition covers the most current information on DMC policies issues in monitoring trials using new designs and recent trial publications relevant to DMC decision making. Presents practical advice for those managing and conducting clinical trials and serving on Data Monitoring Committees. Illustrates the types of challenging issues Data Monitoring Committees face in practical situations. Provides updated and expanded coverage of topics including regulatory and funding agency guidelines and trial designs and their associated demands and limitations. Includes a new chapter addressing legal issues that affect DMC members and discusses general litigation concerns relevant

to clinical research Expands treatment of current journal publications addressing DMC issues Data Monitoring Committees in Clinical Trials A Practical Perspective 2nd Edition is a must have text for anyone engaged in DMC activities as well as trial sponsors clinical trial researchers regulatory and bioethics professionals and those associated with clinical trials in academic government and industry settings *How to Design, Analyse and Report Cluster Randomised Trials in Medicine and Health Related Research* Michael J. Campbell,Stephen J. Walters,2014-03-28 A complete guide to understanding cluster randomised trials Written by two researchers with extensive experience in the field this book presents a complete guide to the design analysis and reporting of cluster randomised trials It spans a wide range of applications trials in developing countries trials in primary care trials in the health services A key feature is the use of R code and code from other popular packages to plan and analyse cluster trials using data from actual trials The book contains clear technical descriptions of the models used and considers in detail the ethics involved in such trials and the problems in planning them For readers and students who do not intend to run a trial but wish to be a critical reader of the literature there are sections on the CONSORT statement and exercises in reading published trials Written in a clear accessible style Features real examples taken from the authors extensive practitioner experience of designing and analysing clinical trials Demonstrates the use of R Stata and SPSS for statistical analysis Includes computer code so the reader can replicate all the analyses Discusses neglected areas such as ethics and practical issues in running cluster randomised trials *How to Design Analyse and Report Cluster Randomised Trials in Medicine and Health Related Research* provides an excellent reference tool and can be read with profit by statisticians health services researchers systematic reviewers and critical readers of cluster randomised trials

Handbook of Field Experiments Esther Duflo,Abhijit Banerjee,2017-03-21 *Handbook of Field Experiments* provides tactics on how to conduct experimental research also presenting a comprehensive catalog on new results from research and areas that remain to be explored This updated addition to the series includes an entire chapters on field experiments the politics and practice of social experiments the methodology and practice of RCTs and the econometrics of randomized experiments These topics apply to a wide variety of fields from politics to education and firm productivity providing readers with a resource that sheds light on timely issues such as robustness and external validity Separating itself from circumscribed debates of specialists this volume surpasses in usefulness the many journal articles and narrowly defined books written by practitioners Balances methodological insights with analyses of principal findings and suggestions for further research Appeals broadly to social scientists seeking to develop an expertise in field experiments Strives to be analytically rigorous Written in language that is accessible to graduate students and non specialist economists [Bayesian Causal Survival Analysis in Clinical Trials with Noncompliance](#) Fang Li,1999 *Journal of the American Statistical Association* ,2004 A scientific and educational journal not only for professional statisticians but also for economists business executives research directors government officials university professors and others who are seriously interested in the application of statistical methods to practical problems in

the development of more useful methods and in the improvement of basic statistical data Statistica Sinica ,2009
Proceedings of the Biometrics Section American Statistical Association. Biometrics Section,1998 Time-dependent Dynamics of Noncompliance and Risk in Clinical Trials Bingbing Li,2005 AMSTAT News American Statistical Association,2002 Estimating Treatment Effect in the Presence of Noncompliance Measured with Error Leslie Anne Kenna,2001 **Bulletin de L'Institut International de Statistique** ,2001 American Doctoral Dissertations ,2001
Dissertation Abstracts International ,2008 **Wiley Encyclopedia of Clinical Trials** Lisa Marie Sullivan,Joseph Massaro,2008 Here you ll find more than 500 entries from the world s leading experts in the field on the basic concepts methodologies and applications in clinical trials The range of topics includes basic statistical concepts design and analysis of clinical trials ethics regulatory issues and methodologies for clinical data management and analysis **Hematopoietic Stem Cell Therapy** Edward David Ball,Ping Law,2000 This book will be the only current practical guide to a widely used procedure for treating leukemias and disseminated cancers The contents are organized chronologically to serve as a step by step guide throughout the transplant process Comprehensive yet concise it emphasizes the latest techniques such as peripheral blood stem cell grafts **Fundamentals of Biostatistics** Bernard A. Rosner,2000 Bernard Rosner s FUNDAMENTALS OF BIOSTATISTICS is a practical introduction to the methods techniques and computation of statistics with human subjects It prepares students for their future courses and careers by introducing the statistical methods most often used in medical literature Rosner minimizes the amount of mathematical formulation algebra based while still giving complete explanations of all the important concepts As in previous editions a major strength of this book is that every new concept is developed systematically through completely worked out examples from current medical research problems **Statistical Theory and Method Abstracts** ,2001

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