

Statistical Methods For Dynamic Treatment Regimes Reinforcement Learning Causal Inference And Personalized Medicine Statistics For Biology And Health

This volume covers classic as well as cutting-edge topics on the analysis of clinical trial data in biomedical and psychosocial research and discusses each topic in an expository and user-friendly fashion. The intent of the book is to provide an overview of the primary statistical and data analytic issues associated with each of the selected topics, followed by a discussion of approaches for tackling such issues and available software packages for carrying out analyses. While classic topics such as survival data analysis, analysis of diagnostic test data and assessment of measurement reliability are well known and covered in depth by available topic-specific texts, this volume serves a different purpose: it provides a quick introduction to each topic for self-learning, particularly for those who have not done any formal coursework on a given topic but must learn it due to its relevance to their multidisciplinary research. In addition, the chapters on these classic topics will reflect issues particularly relevant to modern clinical trials such as longitudinal designs and new methods for analyzing data from such study designs. The coverage of these topics provides a quick introduction to these important statistical issues and methods for addressing them. As with the classic topics, this part of the volume on modern topics will enable researchers to grasp the statistical methods for addressing these emerging issues underlying modern clinical trials and to apply them to their research studies.

These techniques include estimation of regression parameters in the familiar (multivariate) generalized linear regression and multiplicative intensity models. They go beyond standard statistical approaches by incorporating all the observed data to allow for informative censoring, to obtain maximal efficiency, and by developing estimators of causal effects.

Statistical Methods for Dynamic Treatment Regimes shares state of the art of statistical methods developed to address questions of estimation and inference for dynamic treatment regimes, a branch of personalized medicine. This volume demonstrates these methods with their conceptual underpinnings and illustration through analysis of real and simulated data. These methods are immediately applicable to the practice of personalized medicine, which is a medical paradigm that emphasizes the systematic use of individual patient information to optimize patient health care. This is the first single source to provide an overview of methodology and results gathered from journals, proceedings, and technical reports with the goal of orienting researchers to the field. The first chapter establishes context for the statistical reader in the landscape of personalized medicine. Readers need only have familiarity with elementary calculus, linear algebra, and basic large-sample theory to use this text. Throughout the text, authors direct readers to available code or packages in different statistical languages to facilitate implementation. In cases where code does not already exist, the authors provide analytic approaches in sufficient detail that any researcher with knowledge of statistical programming could implement the methods from scratch. This will be an important volume for a wide range of researchers, including statisticians, epidemiologists, medical researchers, and machine learning researchers interested in medical applications. Advanced graduate students in statistics and biostatistics will also find material in Statistical Methods for Dynamic Treatment Regimes to be a critical part of their studies.

Although many books currently available describe statistical models and methods for analyzing longitudinal data, they do not highlight connections between various research threads in the statistical literature. Responding to this void, Longitudinal Data Analysis provides a clear, comprehensive, and unified overview of state-of-the-art theory and applications. It also focuses on the assorted challenges that arise in analyzing longitudinal data. After discussing historical aspects, leading researchers explore four broad themes: parametric modeling, nonparametric and semiparametric methods, joint models, and incomplete data. Each of these sections begins with an introductory chapter that provides useful background material and a broad outline to set the stage for subsequent chapters. Rather than focus on a narrowly defined topic, chapters integrate important research discussions from the statistical literature. They seamlessly blend theory with applications and include examples and case studies from various disciplines. Destined to become a landmark publication in the field, this carefully edited collection emphasizes statistical models and methods likely to endure in the future. Whether involved in the development of statistical methodology or the analysis of longitudinal data, readers will gain new perspectives on the field.

Drug development is the process of finding and producing therapeutically useful pharmaceuticals, turning them into safe and effective medicine, and producing reliable information regarding the appropriate dosage and dosing intervals. With regulatory authorities demanding increasingly higher standards in such developments, statistics has become an intrinsic and critical element in the design and conduct of drug development programmes. Statistical Issues in Drug Development presents an essential and thought provoking guide to the statistical issues and controversies involved in drug development. This highly readable second edition has been updated to include: Comprehensive coverage of the design and interpretation of clinical trials. Expanded sections on missing data, equivalence, meta-analysis and dose finding. An examination of both Bayesian and frequentist methods. A new chapter on pharmacogenomics and expanded coverage of pharmaco-epidemiology and pharmaco-economics. Coverage of the ICH guidelines, in particular ICH E9, Statistical Principles for Clinical Trials. It is hoped that the book will stimulate dialogue between statisticians and life scientists working within the pharmaceutical industry. The accessible and wide-ranging coverage make it essential reading for both statisticians and non-statisticians working in the pharmaceutical industry, regulatory bodies and medical research institutes. There is also much to benefit undergraduate and postgraduate students whose courses include a medical statistics component.

A coherent introductory text from a groundbreaking researcher, focusing on clarity and motivation to build intuition and understanding.

There is a huge amount of literature on statistical models for the prediction of survival after diagnosis of a wide range of diseases like cancer, cardiovascular disease, and chronic kidney disease. Current practice is to use prediction models based on the Cox proportional hazards model and to present those as static models for remaining lifetime after diagnosis or treatment. In contrast, *Dynamic Prediction in Clinical Survival Analysis* focuses on dynamic models for the remaining lifetime at later points in time, for instance using landmark models. Designed to be useful to applied statisticians and clinical epidemiologists, each chapter in the book has a practical focus on the issues of working with real life data. Chapters conclude with additional material either on the interpretation of the models, alternative models, or theoretical background. The book consists of four parts: Part I deals with prognostic models for survival data using (clinical) information available at baseline, based on the Cox model Part II is about prognostic models for survival data using (clinical) information available at baseline, when the proportional hazards assumption of the Cox model is violated Part III is dedicated to the use of time-dependent information in dynamic prediction Part IV explores dynamic prediction models for survival data using genomic data *Dynamic Prediction in Clinical Survival Analysis* summarizes cutting-edge research on the dynamic use of predictive models with traditional and new approaches. Aimed at applied statisticians who actively analyze clinical data in collaboration with clinicians, the analyses of the different data sets throughout the book demonstrate how predictive models can be obtained from proper data sets.

Dynamic Treatment Regimes: Statistical Methods for Precision Medicine provides a comprehensive introduction to statistical methodology for the evaluation and discovery of dynamic treatment regimes from data. Researchers and graduate students in statistics, data science, and related quantitative disciplines with a background in probability and statistical inference and popular statistical modeling techniques will be prepared for further study of this rapidly evolving field. A dynamic treatment regime is a set of sequential decision rules, each corresponding to a key decision point in a disease or disorder process, where each rule takes as input patient information and returns the treatment option he or she should receive. Thus, a treatment regime formalizes how a clinician synthesizes patient information and selects treatments in practice. Treatment regimes are of obvious relevance to precision medicine, which involves tailoring treatment selection to patient characteristics in an evidence-based way. Of critical importance to precision medicine is estimation of an optimal treatment regime, one that, if used to select treatments for the patient population, would lead to the most beneficial outcome on average. Key methods for estimation of an optimal treatment regime from data are motivated and described in detail. A dedicated companion website presents full accounts of application of the methods using a comprehensive R package developed by the authors. The authors' website www.dtr-book.com includes updates, corrections, new papers, and links to useful websites.

Interpersonal phenomena such as attachment, conflict, person perception, learning, and influence have traditionally been studied by examining individuals in isolation, which falls short of capturing their truly interpersonal nature. This book offers state-of-the-art solutions to this age-old problem by presenting methodological and data-analytic approaches useful in investigating processes that take place among dyads: couples, coworkers, parent and child, teacher and student, or doctor and patient, to name just a few. Rich examples from psychology and across the behavioral and social sciences help build the researcher's ability to conceptualize relationship processes; model and test for actor effects, partner effects, and relationship effects; and model and control for the statistical interdependence that can exist between partners. The companion website provides clarifications, elaborations, corrections, and data and files for each chapter.

This book presents computational tools and design principles for piles used in a wide range of applications and for different loading conditions. The chapters provide a mixture of basic engineering solutions and latest research findings in a balanced manner. The chapters are written by top experts in the field. The materials are presented in a unified manner based on both simplified and rigorous numerical methods. The first four chapters present the basic elements and steps in analysis of piles under static and cyclic loading together with clear references to the appropriate design regulations in Eurocode 7 when relevant. The analysis techniques cover conventional code-based methods, solutions based on pile-soil interaction springs, and advanced 3D finite element methods. The applications range from conventional piles to large circular steel piles used as anchors or monopiles in offshore applications. Chapters 5 to 10 are devoted to dynamic and earthquake analyses and design. These chapters cover a range of solutions from dynamic pile-soil springs to elasto-dynamic solutions of large pile groups. Both linear and nonlinear soil behaviours are considered along with response due to dynamic loads and earthquake shaking including possible liquefaction. The book is unique in its unified treatment of the solutions used for static and dynamic analysis of piles with practical examples of application. The book is considered a valuable tool for practicing engineers, graduate students and researchers.

Computer simulation experiments are essential to modern scientific discovery, whether that be in physics, chemistry, biology, epidemiology, ecology, engineering, etc. Surrogates are meta-models of computer simulations, used to solve mathematical models that are too intricate to be worked by hand. Gaussian process (GP) regression is a supremely flexible tool for the analysis of computer simulation experiments. This book presents an applied introduction to GP regression for modelling and optimization of computer simulation experiments. Features:

- Emphasis on methods, applications, and reproducibility.
- R code is integrated throughout for application of the methods.
- Includes more than 200 full colour figures.
- Includes many exercises to supplement understanding, with separate solutions available from the author.
- Supported by a website with full code available to reproduce all methods and examples.

The book is primarily designed as a textbook for postgraduate students studying GP regression from mathematics, statistics, computer science, and engineering. Given the breadth of examples, it could also be used by researchers from these fields, as well as from economics, life science, social

science, etc.

Designing algorithms to recommend items such as news articles and movies to users is a challenging task in numerous web applications. The crux of the problem is to rank items based on users' responses to different items to optimize for multiple objectives. Major technical challenges are high dimensional prediction with sparse data and constructing high dimensional sequential designs to collect data for user modeling and system design. This comprehensive treatment of the statistical issues that arise in recommender systems includes detailed, in-depth discussions of current state-of-the-art methods such as adaptive sequential designs (multi-armed bandit methods), bilinear random-effects models (matrix factorization) and scalable model fitting using modern computing paradigms like MapReduce. The authors draw upon their vast experience working with such large-scale systems at Yahoo! and LinkedIn, and bridge the gap between theory and practice by illustrating complex concepts with examples from applications they are directly involved with. The finite element, an approximation method for solving differential equations of mathematical physics, is a highly effective technique in the analysis and design, or synthesis, of structural dynamic systems. Starting from the system differential equations and its boundary conditions, what is referred to as a weak form of the problem (elaborated in the text) is developed in a variational sense. This variational statement is used to define elemental properties that may be written as matrices and vectors as well as to identify primary and secondary boundaries and all possible boundary conditions. Specific equilibrium problems are also solved. This book clearly reveals the effectiveness and great significance of the finite element method available and the essential role it will play in the future as further development occurs.

Survival analysis arises in many fields of study including medicine, biology, engineering, public health, epidemiology, and economics. This book provides a comprehensive treatment of Bayesian survival analysis. It presents a balance between theory and applications, and for each class of models discussed, detailed examples and analyses from case studies are presented whenever possible. The applications are all from the health sciences, including cancer, AIDS, and the environment.

A user-friendly introduction to some of the most useful analytical tools for model building, estimation, and analysis, presenting key methods and examples. Simulation modeling is increasingly integrated into research and policy analysis of complex sociotechnical systems in a variety of domains. Model-based analysis and policy design inform a range of applications in fields from economics to engineering to health care. This book offers a hands-on introduction to key analytical methods for dynamic modeling. Bringing together tools and methodologies from fields as diverse as computational statistics, econometrics, and operations research in a single text, the book can be used for graduate-level courses and as a reference for dynamic modelers who want to expand their methodological toolbox. The focus is on quantitative techniques for use by dynamic modelers during model construction and analysis, and the material presented is accessible to readers with a background in college-level calculus and statistics. Each chapter describes a key method, presenting an introduction that emphasizes the basic intuition behind each method, tutorial style examples, references to key literature, and exercises. The chapter authors are all experts in the tools and methods they present. The book covers estimation of model parameters using quantitative data; understanding the links between model structure and its behavior; and decision support and optimization. An online appendix offers computer code for applications, models, and solutions to exercises. Contributors Wenyi An, Edward G. Anderson Jr., Yaman Barlas, Nishesh Chalise, Robert Eberlein, Hamed Ghodusi, Winfried Grassmann, Peter S. Hovmand, Mohammad S. Jalali, Nitin Joglekar, David Keith, Juxin Liu, Erling Moxnes, Rogelio Oliva, Nathaniel D. Osgood, Hazhir Rahmandad, Raymond Spiteri, John Sterman, Jeroen Struben, Burcu Tan, Karen Yee, Gönenç Yücel

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Medical Risk Prediction Models: With Ties to Machine Learning is a hands-on book for clinicians, epidemiologists, and professional statisticians who need to make or evaluate a statistical prediction model based on data. The subject of the book is the patient's individualized probability of a medical event within a given time horizon. Gerds and Kattan describe the mathematical details of making and evaluating a statistical prediction model in a highly pedagogical manner while avoiding mathematical notation. Read this book when you are in doubt about whether a Cox regression model predicts better than a random survival forest. Features: All you need to know to correctly make an online risk calculator from scratch Discrimination, calibration, and predictive performance with censored data and competing risks R-code and illustrative examples Interpretation of prediction performance via benchmarks Comparison and combination of rival modeling strategies via cross-validation Thomas A. Gerds is a professor at the Biostatistics Unit at

the University of Copenhagen and is affiliated with the Danish Heart Foundation. He is the author of several R-packages on CRAN and has taught statistics courses to non-statisticians for many years. Michael W. Kattan is a highly cited author and Chair of the Department of Quantitative Health Sciences at Cleveland Clinic. He is a Fellow of the American Statistical Association and has received two awards from the Society for Medical Decision Making: the Eugene L. Saenger Award for Distinguished Service, and the John M. Eisenberg Award for Practical Application of Medical Decision-Making Research.

In an age where the amount of data collected from brain imaging is increasing constantly, it is of critical importance to analyse those data within an accepted framework to ensure proper integration and comparison of the information collected. This book describes the ideas and procedures that underlie the analysis of signals produced by the brain. The aim is to understand how the brain works, in terms of its functional architecture and dynamics. This book provides the background and methodology for the analysis of all types of brain imaging data, from functional magnetic resonance imaging to magnetoencephalography. Critically, Statistical Parametric Mapping provides a widely accepted conceptual framework which allows treatment of all these different modalities. This rests on an understanding of the brain's functional anatomy and the way that measured signals are caused experimentally. The book takes the reader from the basic concepts underlying the analysis of neuroimaging data to cutting edge approaches that would be difficult to find in any other source. Critically, the material is presented in an incremental way so that the reader can understand the precedents for each new development. This book will be particularly useful to neuroscientists engaged in any form of brain mapping; who have to contend with the real-world problems of data analysis and understanding the techniques they are using. It is primarily a scientific treatment and a didactic introduction to the analysis of brain imaging data. It can be used as both a textbook for students and scientists starting to use the techniques, as well as a reference for practicing neuroscientists. The book also serves as a companion to the software packages that have been developed for brain imaging data analysis. An essential reference and companion for users of the SPM software Provides a complete description of the concepts and procedures entailed by the analysis of brain images Offers full didactic treatment of the basic mathematics behind the analysis of brain imaging data Stands as a compendium of all the advances in neuroimaging data analysis over the past decade Adopts an easy to understand and incremental approach that takes the reader from basic statistics to state of the art approaches such as Variational Bayes Structured treatment of data analysis issues that links different modalities and models Includes a series of appendices and tutorial-style chapters that makes even the most sophisticated approaches accessible

"This is truly an outstanding book. [It] brings together all of the latest research in clinical trials methodology and how it can be applied to drug development.... Chang et al provide applications to industry-supported trials. This will allow statisticians in the industry community to take these methods seriously." Jay Herson, Johns Hopkins University The pharmaceutical industry's approach to drug discovery and development has rapidly transformed in the last decade from the more traditional Research and Development (R & D) approach to a more innovative approach in which strategies are employed to compress and optimize the clinical development plan and associated timelines. However, these strategies are generally being considered on an individual trial basis and not as part of a fully integrated overall development program. Such optimization at the trial level is somewhat near-sighted and does not ensure cost, time, or development efficiency of the overall program. This book seeks to address this imbalance by establishing a statistical framework for overall/global clinical development optimization and providing tactics and techniques to support such optimization, including clinical trial simulations. Provides a statistical framework for achieve global optimization in each phase of the drug development process. Describes specific techniques to support optimization including adaptive designs, precision medicine, survival-endpoints, dose finding and multiple testing. Gives practical approaches to handling missing data in clinical trials using SAS. Looks at key controversial issues from both a clinical and statistical perspective. Presents a generous number of case studies from multiple therapeutic areas that help motivate and illustrate the statistical methods introduced in the book. Puts great emphasis on software implementation of the statistical methods with multiple examples of software code (both SAS and R). It is important for statisticians to possess a deep knowledge of the drug development process beyond statistical considerations. For these reasons, this book incorporates both statistical and "clinical/medical" perspectives.

STATISTICAL METHODS FOR PSYCHOLOGY surveys the statistical techniques commonly used in the behavioral and social sciences, particularly psychology and education. To help students gain a better understanding of the specific statistical hypothesis tests that are covered throughout the text, author David Howell emphasizes conceptual understanding. This Eighth Edition continues to focus students on two key themes that are the cornerstones of this book's success: the importance of looking at the data before beginning a hypothesis test, and the importance of knowing the relationship between the statistical test in use and the theoretical questions being asked by the experiment. New and expanded topics--reflecting the evolving realm of statistical methods--include effect size, meta-analysis, and treatment of missing data. Important Notice: Media content referenced within the product description or the product text may not be available in the ebook version.

This book describes statistical techniques for the design and evaluation of research studies on medical diagnostic tests, screening tests, biomarkers and new technologies for classification and prediction in medicine.

Praise for the first edition: "Given the author's years of experience as a statistician and as a founder of the first DMC in pharmaceutical industry trials, I highly recommend this book—not only for experts because of its cogent and organized presentation, but more importantly for young investigators who are seeking information about the logistical and philosophical aspects of a DMC." -S. T. Ounpraseuth, *The American Statistician* In the first edition of this well-regarded book, the author provided a groundbreaking and definitive

guide to best practices in pharmaceutical industry data monitoring committees (DMCs). Maintaining all the material from the first edition and adding substantial new material, *Data and Safety Monitoring Committees in Clinical Trials, Second Edition* is ideal for training professionals to serve on their first DMC as well as for experienced clinical and biostatistical DMC members, sponsor and regulatory agency staff. The second edition guides the reader through newly emerging DMC responsibilities brought about by regulations emphasizing risk vs benefit and the emergence of risk-based monitoring. It also provides the reader with many new statistical methods, clinical trial designs and clinical terminology that have emerged since the first edition. The references have been updated and the very popular end-of-chapter Q&A section has been supplemented with many new experiences since the first edition. New to the Second Edition: Presents statistical methods, tables, listings and graphs appropriate for safety review, efficacy analysis and risk vs benefit analysis, SPERT and PRISMA initiatives. Newly added interim analysis for efficacy and futility section. DMC responsibilities in SUSARs (Serious Unexpected Serious Adverse Reactions), basket trials, umbrella trials, dynamic treatment strategies /SMART trials, pragmatic trials, biosimilar trials, companion diagnostics, etc. DMC responsibilities for data quality and fraud detection (Fraud Recovery Plan) Use of patient reported outcomes of safety Use of meta analysis and data outside the trial New ideas for training and compensation of DMC members Jay Herson is Senior Associate, Biostatistics, Johns Hopkins Bloomberg School of Public Health where he teaches courses on clinical trials and drug development based on his many years experience in clinical trials in academia and the pharmaceutical industry.

Precise dynamic models of processes are required for many applications, ranging from control engineering to the natural sciences and economics. Frequently, such precise models cannot be derived using theoretical considerations alone. Therefore, they must be determined experimentally. This book treats the determination of dynamic models based on measurements taken at the process, which is known as system identification or process identification. Both offline and online methods are presented, i.e. methods that post-process the measured data as well as methods that provide models during the measurement. The book is theory-oriented and application-oriented and most methods covered have been used successfully in practical applications for many different processes. Illustrative examples in this book with real measured data range from hydraulic and electric actuators up to combustion engines. Real experimental data is also provided on the Springer webpage, allowing readers to gather their first experience with the methods presented in this book. Among others, the book covers the following subjects: determination of the non-parametric frequency response, (fast) Fourier transform, correlation analysis, parameter estimation with a focus on the method of Least Squares and modifications, identification of time-variant processes, identification in closed-loop, identification of continuous time processes, and subspace methods. Some methods for nonlinear system identification are also considered, such as the Extended Kalman filter and neural networks. The different methods are compared by using a real three-mass oscillator process, a model of a drive train. For many identification methods, hints for the practical implementation and application are provided. The book is intended to meet the needs of students and practicing engineers working in research and development, design and manufacturing.

Missing data affect nearly every discipline by complicating the statistical analysis of collected data. But since the 1990s, there have been important developments in the statistical methodology for handling missing data. Written by renowned statisticians in this area, *Handbook of Missing Data Methodology* presents many methodological advances and the latest applications of missing data methods in empirical research. Divided into six parts, the handbook begins by establishing notation and terminology. It reviews the general taxonomy of missing data mechanisms and their implications for analysis and offers a historical perspective on early methods for handling missing data. The following three parts cover various inference paradigms when data are missing, including likelihood and Bayesian methods; semi-parametric methods, with particular emphasis on inverse probability weighting; and multiple imputation methods. The next part of the book focuses on a range of approaches that assess the sensitivity of inferences to alternative, routinely non-verifiable assumptions about the missing data process. The final part discusses special topics, such as missing data in clinical trials and sample surveys as well as approaches to model diagnostics in the missing data setting. In each part, an introduction provides useful background material and an overview to set the stage for subsequent chapters. Covering both established and emerging methodologies for missing data, this book sets the scene for future research. It provides the framework for readers to delve into research and practical applications of missing data methods.

The methods of statistical physics have become increasingly important in recent years for the treatment of a variety of diverse physical problems. Of principal interest is the microscopic description of the dynamics of dissipative systems. Although a unified theoretical description has at present not yet been achieved, we have assumed the task of writing a textbook which summarizes those of the most important methods which are self-contained and complete in themselves. We cannot, of course, claim to have treated the field exhaustively. A microscopic description of physical phenomena must necessarily be based upon quantum theory, and we have therefore carried out the treatment of dynamic processes strictly within a quantum-theoretical framework. For this reason alone it was necessary to omit a number of extremely important theories which have up to now been formulated only in terms of classical statistics. The goal of this book is, on the one hand, to give an introduction to the general principles of the quantum statistics of dynamical processes, and, on the other, to provide readers who are interested in the treatment of particular phenomena with methods for solving specific problems. The theory is for the most part formulated within the calculational frame work of Liouville space, which, together with projector formalism, has become an expedient mathematical tool in statistical physics.

A guide to data collection, modeling and inference strategies for biological survey data using Bayesian and classical statistical methods. This book describes a general and flexible framework for modeling and inference in ecological systems based on hierarchical models, with a strict focus on the use of probability models and parametric inference. Hierarchical models represent a paradigm shift in the application of statistics to ecological inference problems because they combine explicit models of ecological system structure or dynamics with models of how ecological

systems are observed. The principles of hierarchical modeling are developed and applied to problems in population, metapopulation, community, and metacommunity systems. The book provides the first synthetic treatment of many recent methodological advances in ecological modeling and unifies disparate methods and procedures. The authors apply principles of hierarchical modeling to ecological problems, including * occurrence or occupancy models for estimating species distribution * abundance models based on many sampling protocols, including distance sampling * capture-recapture models with individual effects * spatial capture-recapture models based on camera trapping and related methods * population and metapopulation dynamic models * models of biodiversity, community structure and dynamics * Wide variety of examples involving many taxa (birds, amphibians, mammals, insects, plants) * Development of classical, likelihood-based procedures for inference, as well as Bayesian methods of analysis * Detailed explanations describing the implementation of hierarchical models using freely available software such as R and WinBUGS * Computing support in technical appendices in an online companion web site

Forecasting is required in many situations. Stocking an inventory may require forecasts of demand months in advance. Telecommunication routing requires traffic forecasts a few minutes ahead. Whatever the circumstances or time horizons involved, forecasting is an important aid in effective and efficient planning. This textbook provides a comprehensive introduction to forecasting methods and presents enough information about each method for readers to use them sensibly.

This book provides an overview of the theories and applications on subgroups in the biopharmaceutical industry. Drawing from a range of expert perspectives in academia and industry, this collection offers an overarching dialogue about recent advances in biopharmaceutical applications, novel statistical and methodological developments, and potential future directions. The volume covers topics in subgroups in clinical trial design; subgroup identification and personalized medicine; and general issues in subgroup analyses, including regulatory ones. Included chapters present current methods, theories, and case applications in the diverse field of subgroup application and analysis. Offering timely perspectives from a range of authoritative sources, the volume is designed to have wide appeal to professionals in the pharmaceutical industry and to graduate students and researchers in academe and government.

This book illustrates numerous statistical practices that are commonly used by medical researchers, but which have severe flaws that may not be obvious. For each example, it provides one or more alternative statistical methods that avoid misleading or incorrect inferences being made. The technical level is kept to a minimum to make the book accessible to non-statisticians. At the same time, since many of the examples describe methods used routinely by medical statisticians with formal statistical training, the book appeals to a broad readership in the medical research community.

Many racial and ethnic groups in the United States, including blacks, Hispanics, Asians, American Indians, and others, have historically faced severe discrimination—pervasive and open denial of civil, social, political, educational, and economic opportunities. Today, large differences among racial and ethnic groups continue to exist in employment, income and wealth, housing, education, criminal justice, health, and other areas. While many factors may contribute to such differences, their size and extent suggest that various forms of discriminatory treatment persist in U.S. society and serve to undercut the achievement of equal opportunity. *Measuring Racial Discrimination* considers the definition of race and racial discrimination, reviews the existing techniques used to measure racial discrimination, and identifies new tools and areas for future research. The book conducts a thorough evaluation of current methodologies for a wide range of circumstances in which racial discrimination may occur, and makes recommendations on how to better assess the presence and effects of discrimination.

The world is becoming increasingly complex, with larger quantities of data available to be analyzed. It so happens that much of these "big data" that are available are spatio-temporal in nature, meaning that they can be indexed by their spatial locations and time stamps. *Spatio-Temporal Statistics with R* provides an accessible introduction to statistical analysis of spatio-temporal data, with hands-on applications of the statistical methods using R Labs found at the end of each chapter. The book: Gives a step-by-step approach to analyzing spatio-temporal data, starting with visualization, then statistical modelling, with an emphasis on hierarchical statistical models and basis function expansions, and finishing with model evaluation Provides a gradual entry to the methodological aspects of spatio-temporal statistics Provides broad coverage of using R as well as "R Tips" throughout. Features detailed examples and applications in end-of-chapter Labs Features "Technical Notes" throughout to provide additional technical detail where relevant Supplemented by a website featuring the associated R package, data, reviews, errata, a discussion forum, and more The book fills a void in the literature and available software, providing a bridge for students and researchers alike who wish to learn the basics of spatio-temporal statistics. It is written in an informal style and functions as a down-to-earth introduction to the subject. Any reader familiar with calculus-based probability and statistics, and who is comfortable with basic matrix-algebra representations of statistical models, would find this book easy to follow. The goal is to give as many people as possible the tools and confidence to analyze spatio-temporal data.

In longitudinal studies it is often of interest to investigate how a marker that is repeatedly measured in time is associated with a time to an event of interest, e.g., prostate cancer studies where longitudinal PSA level measurements are collected in conjunction with the time-to-recurrence. *Joint Models for Longitudinal and Time-to-Event Data: With Applications in R* provides a full treatment of random effects joint models for longitudinal and time-to-event outcomes that can be utilized to analyze such data. The content is primarily explanatory, focusing on applications of joint modeling, but sufficient mathematical details are provided to facilitate understanding of the key features of these models. All illustrations put forward can be implemented in the R programming language via the freely available package JM written by the author. All the R code used in the book is available at: <http://jmr.r-forge.r-project.org/>

Statistical Methods in the Atmospheric Sciences, Third Edition, explains the latest statistical methods used to describe, analyze, test, and forecast atmospheric data. This revised and expanded text is intended to help students understand and communicate what their data sets have to say, or to make sense of the scientific literature in meteorology, climatology, and related disciplines. In this new edition, what was a single chapter on multivariate statistics has been expanded to a full six chapters on this important topic. Other chapters have also been revised and cover exploratory data analysis, probability distributions, hypothesis testing, statistical weather forecasting, forecast verification, and time series analysis. There is now an expanded treatment of resampling tests and key analysis techniques, an updated discussion on ensemble forecasting, and a detailed chapter on forecast verification. In addition, the book includes new sections on maximum likelihood and on statistical simulation and contains current references to original research.

Students will benefit from pedagogical features including worked examples, end-of-chapter exercises with separate solutions, and numerous illustrations and equations. This book will be of interest to researchers and students in the atmospheric sciences, including meteorology, climatology, and other geophysical disciplines. Accessible presentation and explanation of techniques for atmospheric data summarization, analysis, testing and forecasting Many worked examples End-of-chapter exercises, with answers provided Personalized medicine is a medical paradigm that emphasizes systematic use of individual patient information to optimize that patient's health care, particularly in managing chronic conditions and treating cancer. In the statistical literature, sequential decision making is known as an adaptive treatment strategy (ATS) or a dynamic treatment regime (DTR). The field of DTRs emerges at the interface of statistics, machine learning, and biomedical science to provide a data-driven framework for precision medicine. The authors provide a learning-by-seeing approach to the development of ATSs, aimed at a broad audience of health researchers. All estimation procedures used are described in sufficient heuristic and technical detail so that less quantitative readers can understand the broad principles underlying the approaches. At the same time, more quantitative readers can implement these practices. This book provides the most up-to-date summary of the current state of the statistical research in personalized medicine; contains chapters by leaders in the area from both the statistics and computer sciences fields; and also contains a range of practical advice, introductory and expository materials, and case studies.

Statistical Methods for Dynamic Treatment Regimes Reinforcement Learning, Causal Inference, and Personalized Medicine Springer Science & Business Media

Trends and Changes in Hydroclimatic Variables: Links to Climate Variability and Change discusses the change detection and trend analysis methods used to assess hydroclimatic variables in a changing climate. Changes and trends in hydroclimatic variables are assessed using state-of-the-art methods, such as non-linear trend estimation (including spline smoothing and local regression) and handling persistence (or serial auto-correlation in data) for assessing trends in different hydroclimatic variables (e.g. pre-whitening methods). This book offers a variety of real-life case studies and problem-solving techniques for a field that is rapidly evolving. Users will find methods to evaluate points where time series characteristics change and non-homogeneity in time series. In addition, it covers the subject of climate variability and change in an immense level of detail, including changes on precipitation, streamflow and sea levels. Examines statistical methods for trend analysis, providing an excellent reference book for scholars, scientists, students and professionals Offers an exhaustive treatment of several hydroclimatic variables in one book, providing readers with a comprehensive understanding of changes in hydroclimatic variables over time and space Presents case studies dealing with changes in hydroclimatic variables in different geographical regions of the world Focuses on climate variability and change, including an extensive assessment of trends and their associated links to climate variability and change

Reliably optimizing a new treatment in humans is a critical first step in clinical evaluation since choosing a suboptimal dose or schedule may lead to failure in later trials. At the same time, if promising preclinical results do not translate into a real treatment advance, it is important to determine this quickly and terminate the clinical evaluation process to avoid wasting resources. Bayesian Designs for Phase I–II Clinical Trials describes how phase I–II designs can serve as a bridge or protective barrier between preclinical studies and large confirmatory clinical trials. It illustrates many of the severe drawbacks with conventional methods used for early-phase clinical trials and presents numerous Bayesian designs for human clinical trials of new experimental treatment regimes. Written by research leaders from the University of Texas MD Anderson Cancer Center, this book shows how Bayesian designs for early-phase clinical trials can explore, refine, and optimize new experimental treatments. It emphasizes the importance of basing decisions on both efficacy and toxicity.

Statistical concepts provide scientific framework in experimental studies, including randomized controlled trials. In order to design, monitor, analyze and draw conclusions scientifically from such clinical trials, clinical investigators and statisticians should have a firm grasp of the requisite statistical concepts. The Handbook of Statistical Methods for Randomized Controlled Trials presents these statistical concepts in a logical sequence from beginning to end and can be used as a textbook in a course or as a reference on statistical methods for randomized controlled trials. Part I provides a brief historical background on modern randomized controlled trials and introduces statistical concepts central to planning, monitoring and analysis of randomized controlled trials. Part II describes statistical methods for analysis of different types of outcomes and the associated statistical distributions used in testing the statistical hypotheses regarding the clinical questions. Part III describes some of the most used experimental designs for randomized controlled trials including the sample size estimation necessary in planning. Part IV describe statistical methods used in interim analysis for monitoring of efficacy and safety data. Part V describe important issues in statistical analyses such as multiple testing, subgroup analysis, competing risks and joint models for longitudinal markers and clinical outcomes. Part VI addresses selected miscellaneous topics in design and analysis including multiple assignment randomization trials, analysis of safety outcomes, non-inferiority trials, incorporating historical data, and validation of surrogate outcomes.

Discover New Methods for Dealing with High-Dimensional Data A sparse statistical model has only a small number of nonzero parameters or weights; therefore, it is much easier to estimate and interpret than a dense model. Statistical Learning with Sparsity: The Lasso and Generalizations presents methods that exploit sparsity to help recover the underlying signal in a set of data. Top experts in this rapidly evolving field, the authors describe the lasso for linear regression and a simple coordinate descent algorithm for its computation. They discuss the application of l_1 penalties to generalized linear models and support vector machines, cover generalized penalties such as the elastic net and group lasso, and review numerical methods for optimization. They also present statistical inference methods for fitted (lasso) models, including the bootstrap, Bayesian methods, and recently developed approaches. In addition, the book examines matrix decomposition, sparse multivariate analysis, graphical models, and compressed sensing. It concludes

with a survey of theoretical results for the lasso. In this age of big data, the number of features measured on a person or object can be large and might be larger than the number of observations. This book shows how the sparsity assumption allows us to tackle these problems and extract useful and reproducible patterns from big datasets. Data analysts, computer scientists, and theorists will appreciate this thorough and up-to-date treatment of sparse statistical modeling.

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