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Being that pharmacokinetics (PK) is the study of how the body handles various substances, it is not surprising that PK plays an important role in the early development of new drugs. However, the clinical research community widely believes that mathematics in some way blurs the true meaning of PK. Demonstrating that quite the opposite is true, *Computational Pharmacokinetics* outlines the fundamental concepts and models of PK from a mathematical perspective based on clinically relevant parameters. After an introductory chapter, the book presents a noncompartmental approach to PK and discusses the numerical analysis of PK data, including a description of an absorption process through numerical deconvolution. The author then builds a simple physiological model to better understand PK volumes and compares this model to other methods. The book also introduces compartmental models, discusses their limitations, and creates a general-purpose type of model. The final chapter looks at the relationship between drug concentration and effect, known as PK/pharmacodynamics (PD) modeling. With both a solid discussion of theory and the use of practical examples, this book will enable readers to thoroughly grasp the computational factors of PK modeling.

Due to the tremendous accumulation of data for genetic markers, pharmacogenomics, the study of the functions and interactions of all genes in the overall variability of drug response, is one of the hottest areas of research in biomedical science. *Statistical and Computational Pharmacogenomics* presents recent developments in statistical methodology with a number of detailed worked examples that outline how these methods can be applied. This comprehensive volume provides key tools needed to understand and model the genetic variation for drug response and equips statisticians with a thorough understanding of this complex field and how computational skills can be employed.

In cancer research, a traditional phase II trial is designed as a single-arm trial that compares the experimental therapy to a historical control. This simple trial design has led to several adverse issues, including increased false positivity of phase II trial results and negative phase III trials. To rectify these problems, oncologists and biostatisticians have begun to use a randomized phase II trial that compares an experimental therapy with a prospective control therapy. *Randomized Phase II Cancer Clinical Trials* explains how to properly select and accurately use diverse statistical methods for designing and analyzing phase II trials. The author first reviews the statistical methods for single-arm phase II trials since some methodologies for randomized phase II trials stem from single-arm phase II trials and many phase II cancer clinical trials still use single-arm designs. The book then presents methods for randomized phase II trials and describes statistical methods for both single-arm and randomized phase II trials. Although the text focuses on phase II cancer clinical trials, the statistical methods covered can also be used (with minor modifications) in phase II trials for other diseases and in phase III cancer clinical trials. Suitable for cancer clinicians and biostatisticians, this book shows how randomized phase II trials with a prospective control resolve the shortcomings of traditional single-arm phase II trials. It provides readers with numerous statistical design and analysis methods for randomized phase II trials in oncology.

Emphasizing statistical concepts used in medicine, the interpretation of methods, and applications, *Medical Biostatistics, Second Edition* shows how biostatistical methods are important tools in managing uncertainties in medicine and the health sciences. With coverage ranging from elementary topics, such as mean and standard deviation, to advanced approaches, such as logistic regression and multivariate methods, this edition is even more far-reaching in scope than its predecessor. New to the Second Edition Full chapters on clinical trials, observational studies, laboratory experiments, survival analysis, and logistic regression A new chapter on clinimetrics and evidence-based medicine Expanded discussions on epistemic uncertainties, crossover designs, equivalence trials and studies, hazard functions, and the log-rank test The introduction of research evidence, multilevel regression, classification, and regression trees at an elementary level Sample size formulas for relative risk, odds ratio, and survival studies Numerous additional examples from contemporary medical literature Numbered steps for the many procedures and remarks Requiring only high school algebra, this text enables a solid understanding of the statistical concepts required to critically examine medical literature, scientifically plan and carry out medical investigations, and meaningfully analyze data.

Now viewed as its own scientific discipline, clinical trial methodology encompasses the methods required for the protection of participants in a clinical trial and the methods necessary to provide a valid inference about the objective of the trial. Drawing from the authors' courses on the subject as well as the first author's more than 30 years working in the pharmaceutical industry, *Clinical Trial Methodology* emphasizes the importance of statistical thinking in clinical research and presents the methodology as a key component of clinical research. From ethical issues and sample size considerations to adaptive design procedures and statistical analysis, the book first covers the methodology that spans every clinical trial regardless of the area of application. Crucial to the generic drug industry, bioequivalence clinical trials are then discussed. The authors describe a parallel bioequivalence clinical trial of six formulations incorporating group sequential procedures that permit sample size re-estimation. The final chapters incorporate real-world case studies of clinical trials from the authors' own experiences. These examples include a landmark Phase III clinical trial involving the treatment of duodenal ulcers and Phase III clinical trials that contributed to the first drug approved for the treatment of Alzheimer's disease. Aided by the U.S. FDA, the U.S. National Institutes of Health, the pharmaceutical industry, and academia, the area of clinical trial methodology has evolved over the last six decades into a scientific discipline. This guide explores the processes essential for developing and conducting a quality clinical trial protocol and providing quality data collection, biostatistical analyses, and a clinical study report, all while maintaining the highest standards of ethics and excellence.

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Optimal Design for Nonlinear Response Models discusses the theory and applications of model-based experimental design with a strong emphasis on biopharmaceutical studies. The book draws on the authors' many years of experience in academia and the pharmaceutical industry. While the focus is on nonlinear models, the book begins with an explanation of the key ideas, using linear models as examples. Applying the linearization in the parameter space, it then covers nonlinear models and locally optimal designs as well as minimax, optimal on average, and Bayesian designs. The authors also discuss adaptive designs, focusing on procedures with non-informative stopping. The common goals of experimental design—such as reducing costs, supporting efficient decision making, and gaining maximum information under various constraints—are often the same across diverse applied areas. Ethical and regulatory aspects play a much more prominent role in biological, medical, and pharmaceutical research. The authors address all of these issues through many examples in the book.

Written by a biostatistics expert with over 20 years of experience in the field, Bayesian Methods in Epidemiology presents statistical methods used in epidemiology from a Bayesian viewpoint. It employs the software package WinBUGS to carry out the analyses and offers the code in the text and for download online. The book examines study designs that investigate the association between exposure to risk factors and the occurrence of disease. It covers introductory adjustment techniques to compare mortality between states and regression methods to study the association between various risk factors and disease, including logistic regression, simple and multiple linear regression, categorical/ordinal regression, and nonlinear models. The text also introduces a Bayesian approach for the estimation of survival by life tables and illustrates other approaches to estimate survival, including a parametric model based on the Weibull distribution and the Cox proportional hazards (nonparametric) model. Using Bayesian methods to estimate the lead time of the modality, the author explains how to screen for a disease among individuals that do not exhibit any symptoms of the disease. With many examples and end-of-chapter exercises, this book is the first to introduce epidemiology from a Bayesian perspective. It shows epidemiologists how these Bayesian models and techniques are useful in studying the association between disease and exposure to risk factors.

In biostatistical research and courses, practitioners and students often lack a thorough understanding of how to apply statistical methods to synthesize biomedical and clinical trial data. Filling this knowledge gap, Applied Meta-Analysis with R shows how to implement statistical meta-analysis methods to real data using R. Drawing on their extensive research and teaching experiences, the authors provide detailed, step-by-step explanations of the implementation of meta-analysis methods using R. Each chapter gives examples of real studies compiled from the literature. After presenting the data and necessary background for understanding the applications, various methods for analyzing meta-data are introduced. The authors then develop analysis code using the appropriate R packages and functions. This systematic approach helps readers thoroughly understand the analysis methods and R implementation, enabling them to use R and the methods to analyze their own meta-data. Suitable as a graduate-level text for a meta-data analysis course, the book is also a valuable reference for practitioners and biostatisticians (even those with little or no experience in using R) in public health, medical research, governmental agencies, and the pharmaceutical industry.

Using real data sets throughout, Survival Analysis in Medicine and Genetics introduces the latest methods for analyzing high-dimensional survival data. It provides thorough coverage of recent statistical developments in the medical and genetics fields. The text mainly addresses special concerns of the survival model. After covering the fundamentals, it discusses interval censoring, nonparametric and semiparametric hazard regression, multivariate survival data analysis, the sub-distribution method for competing risks data, the cure rate model, and Bayesian inference methods. The authors then focus on time-dependent diagnostic medicine and high-dimensional genetic data analysis. Many of the methods are illustrated with clinical examples. Emphasizing the applications of survival analysis techniques in genetics, this book presents a statistical framework for burgeoning research in this area and offers a set of established approaches for statistical analysis. It reveals a new way of looking at how predictors are associated with censored survival time and extracts novel statistical genetic methods for censored survival time outcome from the vast amount of research results in genomics.

Health economics is concerned with the study of the cost-effectiveness of health care interventions. This book provides an overview of Bayesian methods for the analysis of health economic data. After an introduction to the basic economic concepts and methods of evaluation, it presents Bayesian statistics using accessible mathematics. The next chapters describe the theory and practice of cost-effectiveness analysis from a statistical viewpoint, and Bayesian computation, notably MCMC. The final chapter presents three detailed case studies covering cost-effectiveness analyses using individual data from clinical trials, evidence synthesis and hierarchical models and Markov models. The text uses WinBUGS and JAGS with datasets and code available online.

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