

Chapman & Hall/CRC Biostatistics Series

# Exposure-Response Modeling Methods and Practical Implementation



Jixian Wang



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# Exposure Response Modeling Methods And Practical Implementation Chapman Hallcrc Biostatistics Series

**Hongjie Liu**



## **Exposure Response Modeling Methods And Practical Implementation Chapman Hallcrc Biostatistics Series:**

Exposure-Response Modeling Jixian Wang, 2015-07-17 Discover the Latest Statistical Approaches for Modeling Exposure Response Relationships Written by an applied statistician with extensive practical experience in drug development this book explores a wide range of topics in exposure response modeling from traditional PKPD modeling to other areas in drug development and beyond It incorporates numerous examples and software programs for implementing novel methods The book emphasizes dose adjustment and treatment adaptation based on dynamic exposure response models illustrates how to apply causal inference to exposure response modeling in pharmacometrics and epidemiology and links exposure response modeling to clinical decision making through model based decision analysis

Exposure-Response Modeling Jixian Wang, 2015-07-17 Discover the Latest Statistical Approaches for Modeling Exposure Response Relationships Written by an applied statistician with extensive practical experience in drug development this book explores a wide range of topics in exposure response modeling from traditional PKPD modeling to other areas in drug development and beyond It incorporates numerous examples and software programs for implementing novel methods The book emphasizes dose adjustment and treatment adaptation based on dynamic exposure response models illustrates how to apply causal inference to exposure response modeling in pharmacometrics and epidemiology and links exposure response modeling to clinical decision making through model based decision analysis

Dose-Exposure-Response Modeling Jixian Wang, 2026-02-06 This thoroughly revised and updated new edition reflects the progress that has been made in dose exposure response DER modelling As the title suggests the new edition covers more topics on dose and dose adjustment A large part of the book has been rewritten including an updated Bayesian analysis and modeling chapter with new materials on approximate Bayesian modeling with misspecified models Bayesian bootstrap for the cut the feedback approach and meta regression with Stan codes for implementation Two new chapters in this edition include one on causal DER modeling with an introduction to the concept of causal DER relationship approaches such as the generalized propensity score and instrumental control function approaches for adjustment for observed and unobserved confounders and Bayesian causal DER modeling Another new chapter is dedicated to learning DER relationships with the concept and methods of machine learning including applications to adaptive dose finding trials by bandits contextual bandits and Thompson sampling with Bayesian bootstrap adaptive control for tracking using a dynamic model with an application for individual warfarin dosing The new appendix contains non standard materials used in the book Applied statisticians and modelers can find details on how to implement new approaches while researchers can find topics for or applications of their work In addition students can see how complicated methodology and models are applied to practical situations Key Features Provides SAS R and Stan codes that will enable readers to test the approaches in their own scenarios Gives a systematic treatment of concepts and methodology Helps with understanding concepts and evaluating the performance of new methods particularly those in Chapters 7 8 and 9 Includes a large amount of

R codes for methods introduced in the new materials in chapters on Bayesian analyses causal inference and dose adjustment Includes simulation to show how some complex methods such as generalized propensity score adjustment and adaptive dose adjustment can be implemented with simple codes

*Self-Controlled Case Series Studies* Paddy Farrington, Heather Whitaker, Yonas Ghebremichael Weldeselassie, 2018 The self controlled case series SCCS is one of the most important self controlled designs in observational research but has often been misunderstood and even misapplied This book written by the team that has led the development of the SCCS from the beginning is an essential guide to all aspects related to this method Dr Martijn Schuemie OHDSI This book provides the first comprehensive account of the self controlled case series SCCS method a statistical method for investigating associations between outcome events and time varying exposures The method only requires information from individuals who have experienced the event of interest and automatically controls for multiplicative time invariant confounders even when these are unmeasured or unknown It is increasingly being used in epidemiology most frequently to study the safety of vaccines and pharmaceutical drugs Key features of the book include A thorough yet accessible description of the SCCS method with mathematical details provided in separate starred sections Comprehensive discussion of assumptions and how they may be verified A detailed account of different SCCS models extensions of the SCCS method and the design of SCCS studies Extensive practical illustrations and worked examples from epidemiology Full computer code from the associated R package SCCS which includes all the data sets used in the book The book is aimed at a broad range of readers including epidemiologists and medical statisticians who wish to use the SCCS method and also researchers with an interest in statistical methodology The three authors have been closely involved with the inception development popularisation and programming of the SCCS method

*Medical Product Safety Evaluation* Jie Chen, Joseph Heyse, Tze Leung Lai, 2018-09-03 Medical Product Safety Evaluation Biological Models and Statistical Methods presents cutting edge biological models and statistical methods that are tailored to specific objectives and data types for safety analysis and benefit risk assessment Some frequently encountered issues and challenges in the design and analysis of safety studies are discussed with illustrative applications and examples Medical Product Safety Evaluation Biological Models and Statistical Methods presents cutting edge biological models and statistical methods that are tailored to specific objectives and data types for safety analysis and benefit risk assessment Some frequently encountered issues and challenges in the design and analysis of safety studies are discussed with illustrative applications and examples The book is designed not only for biopharmaceutical professionals such as statisticians safety specialists pharmacovigilance experts and pharmacoepidemiologists who can use the book as self learning materials or in short courses or training programs but also for graduate students in statistics and biomedical data science for a one semester course Each chapter provides supplements and problems as more readings and exercises

**Estimands, Estimators and Sensitivity Analysis in Clinical Trials** Craig Mallinckrodt, Geert Molenberghs, Ilya Lipkovich, Bohdana Ratitch, 2019-12-23 The concepts of estimands analyses

estimators and sensitivity are interrelated Therefore great need exists for an integrated approach to these topics This book acts as a practical guide to developing and implementing statistical analysis plans by explaining fundamental concepts using accessible language providing technical details real world examples and SAS and R code to implement analyses The updated ICH guideline raises new analytic and cross functional challenges for statisticians Gaps between different communities have come to surface such as between causal inference and clinical trialists as well as among clinicians statisticians and regulators when it comes to communicating decision making objectives assumptions and interpretations of evidence This book lays out a path toward bridging some of these gaps It offers A common language and unifying framework along with the technical details and practical guidance to help statisticians meet the challenges A thorough treatment of intercurrent events ICEs i e postrandomization events that confound interpretation of outcomes and five strategies for ICEs in ICH E9 R1 Details on how estimands integrated into a principled study development process lay a foundation for coherent specification of trial design conduct and analysis needed to overcome the issues caused by ICEs A perspective on the role of the intention to treat principle Examples and case studies from various areas Example code in SAS and R A connection with causal inference Implications and methods for analysis of longitudinal trials with missing data Together the authors have offered the readers their ample expertise in clinical trial design and analysis from an industrial and academic perspective

*Association Models in Epidemiology* Hongjie Liu, 2024-08-05 *Association Models in Epidemiology Study Designs Modeling Strategies and Analytic Methods* is written by an epidemiologist for graduate students researchers and practitioners who will use regression techniques to analyze data It focuses on association models rather than prediction models The book targets students and working professionals who lack bona fide modeling experts but are committed to conducting appropriate regression analyses and generating valid findings from their projects This book aims to offer detailed strategies to guide them in modeling epidemiologic data Features Custom Tailored Models Discover association models specifically designed for epidemiologic study designs Epidemiologic Principles in Action Learn how to apply and translate epidemiologic principles into regression modeling techniques Model Specification Guidance Get expert guidance on model specifications to estimate exposure outcome associations accurately controlling for confounding bias Accessible Language Explore regression intricacies in user friendly language accompanied by real world examples that make learning easier Step by Step Approach Follow a straightforward step by step approach to master strategies and procedures for analysis Rich in Examples Benefit from 120 examples 77 figures 86 tables and 174 SAS outputs with annotations to enhance your understanding Book website located here Crafted for two primary audiences this text benefits graduate epidemiology students seeking to understand how epidemiologic principles inform modeling analyses and public health professionals conducting independent analyses in their work Therefore this book serves as a textbook in the classroom and as a reference book in the workplace A wealth of supporting material is available for download from the book s CRC Press webpage Upon completing this text readers should

gain confidence in accurately estimating associations between risk factors and outcomes controlling confounding bias and assessing effect modification

**Handbook of Statistical Methods for Case-Control Studies** Ørnulf Borgan, Norman Breslow, Nilanjan Chatterjee, Mitchell H. Gail, Alastair Scott, Chris J. Wild, 2017

Handbook of Statistical Methods for Case Control Studies is written by leading researchers in the field. It provides an in depth treatment of up to date and currently developing statistical methods for the design and analysis of case control studies as well as a review of classical principles and methods. The handbook is designed to serve as a reference text for biostatisticians and quantitatively oriented epidemiologists who are working on the design and analysis of case control studies or on related statistical methods research. Though not specifically intended as a textbook it may also be used as a backup reference text for graduate level courses.

**Book Sections**

Classical designs and causal inference measurement error power and small sample inference Designs that use full cohort information Time to event data Genetic epidemiology

About the Editors

Ørnulf Borgan is Professor of Statistics University of Oslo. His book with Andersen Gill and Keiding on counting processes in survival analysis is a world classic.

Norman E Breslow was at the time of his death Professor Emeritus in Biostatistics University of Washington. For decades his book with Nick Day has been the authoritative text on case control methodology.

Nilanjan Chatterjee is Bloomberg Distinguished Professor Johns Hopkins University. He leads a broad research program in statistical methods for modern large scale biomedical studies.

Mitchell H Gail is a Senior Investigator at the National Cancer Institute. His research includes modeling absolute risk of disease intervention trials and statistical methods for epidemiology.

Alastair Scott was at the time of his death Professor Emeritus of Statistics University of Auckland. He was a major contributor to using survey sampling methods for analyzing case control data.

Chris J Wild is Professor of Statistics University of Auckland. His research includes nonlinear regression and methods for fitting models to response selective data.

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