

Chapman & Hall/CRC Biostatistics Series

Statistical Methods for Drug Safety



Robert D. Gibbons
Anup K. Amatya



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Jay Herson



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Pharmacovigilance - E-BOOK Thao Doan, Fabio Lievano, Linda Scarazzini, Charles Schubert, Barbara Hendrickson, 2024-11-20 Written by multidisciplinary experts in the fields of pharmaceutical and patient safety Pharmacovigilance A Practical Approach Second Edition provides a succinct easy to digest overview of an increasingly critical area of medical safety From cover to cover this concise resource offers essential information for physicians and other health care professionals clinical researchers and regulators who need a comprehensive up to date source of information on the principles and practice of pharmacovigilance Presents vital easy to read cutting edge information on patient safety the pharmacology regulatory landscape and the current and future use of digital technologies Provides up to date coverage of hot topics in the field including pharmacodynamic and safety precision medicine immunogenicity vaccine hesitancy and safety genetic toxicology and adverse events Contains new chapters on pre clinical safety assessment pharmacogenetics first in human trials product aggregate safety assessment data monitoring committees and more Offers new and expanded coverage of pharmacovigilance in early pre clinical drug development through post marketing surveillance as well as a blueprint for training future pharmacovigilance professionals Includes real world case studies to ensure content is relevant and applicable to everyday practice Discusses a range of topics across disciplines and how they relate to pharmacovigilance including behavioral science patient perspectives and risk communication Any

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contract research organization that provided statistical support to nearly seventy five DMCs It explains the difference in DMC operations between the pharmaceutical industry and National Institutes of Health NIH sponsored trials Leading you through the types of reports for adverse events and lab values the author presents the statistical requirements of data monitoring committees and gives advice on how statisticians can best interact with physician members of these committees He also shows how physicians think differently about safety data than statisticians proving that both views are needed

Data Analysis with Competing Risks and Intermediate States Ronald B. Geskus,2015-07-14 This practical and thorough book explains when and how to use models and techniques for the analysis of competing risks and intermediate states It covers the most recent insights on estimation techniques and discusses in detail how to interpret the obtained results Each chapter includes standard exercises a software section on SAS Stata and R and computer practicals that allow readers to practice with the techniques The book s website provides the R code for the computer practicals along with other material

Quantitative Evaluation of Safety in Drug Development Qi Jiang,H. Amy Xia,2014-12-08 State of the Art Methods for Drug Safety AssessmentResponding to the increased scrutiny of drug safety in recent years Quantitative Evaluation of Safety in Drug Development Design Analysis and Reporting explains design monitoring analysis and reporting issues for both clinical trials and observational studies in biopharmaceutical product deve Dynamical Biostatistical Models Daniel Commenges,Helene Jacqmin-Gadda,2015-10-02 Dynamical Biostatistical Models presents statistical models and methods for the analysis of longitudinal data The book focuses on models for analyzing repeated measures of quantitative and qualitative variables and events history including survival and multistate models Most of the advanced methods such as multistate and joint models can be ap *Multiregional Clinical Trials for Simultaneous Global New Drug Development* Joshua Chen,Hui Quan,2016-04-21 In a global clinical development strategy multiregional clinical trials MRCTs are vital in the development of innovative medicines Multiregional Clinical Trials for Simultaneous Global New Drug Development presents a comprehensive overview on the current status of conducting MRCTs in clinical development International experts from academia in

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