1. Record Nr. UNINA9910787843703321

Titolo	Quantitative evaluation of safety in drug development : design, analysis and reporting / / edited by Qi Jiang, Amgen Inc, Thousand Oaks, California, USA; H. Amy Xia, Amgen Inc, Thousand Oaks, California, USA
Pubbl/distr/stampa	Boca Raton : , : CRC Press, , [2015] ©2015
ISBN	0-429-08795-0 1-4665-5547-5
Descrizione fisica	1 online resource (374 p.)
Collana	Chapman and Hall/CRC Biostatistics Series
Disciplina	615.1072/7 615.10727
Soggetti	Drug development
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references at the end of each chapters.
Nota di contenuto	Front Cover; Contents; Preface; Editors; Contributors; Chapter 1: Incorporating Quantitative Safety Evaluation into Risk Management; Chapter 2: Bayesian Meta-Experimental Design for Evaluating Cardiovascular Risk; Chapter 3: Non-Inferiority Study Design and Analysis for Safety Endpoints; Chapter 4: Program Safety Analysis Plan: An Implementation Guide; Chapter 5: Why a DMC Safety Report Differs from a Safety Section Written at the End of the Trial; Chapter 6: Safety Surveillance and Signal Detection Process; Chapter 7: Bayesian Adaptive Trials for Drug Safety Chapter 8: Observational Safety Study Design, Analysis, and ReportingChapter 9: Emerging Role of Observational Health-Care Data in Pharmacovigilance; Chapter 10: Roadmap for Causal Inference in Safety Analysis; Chapter 11: Safety Graphics; Chapter 12: Bayesian Network Meta-Analysis for Safety Evaluation; Chapter 13: Regulatory Issues in Meta-Analysis of Safety Data; Chapter 14: Bayesian Applications for Drug Safety Evaluation; Chapter 15: Risk-Benefit Assessment Approaches; Chapter 16: Detecting Safety Signals in Subgroups Chapter 17: Overview of Safety Evaluation and Quantitative Approaches during Preclinical and Early Phases of Drug DevelopmentBack Cover

Sommario/riassunto	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 development. It presents the latest statistical methods for drug safety assessment. The book's three sections focus on study design, safety monitoring, and data evaluation/analysis. The book addresses key challenges across regulatory agencies, industry,