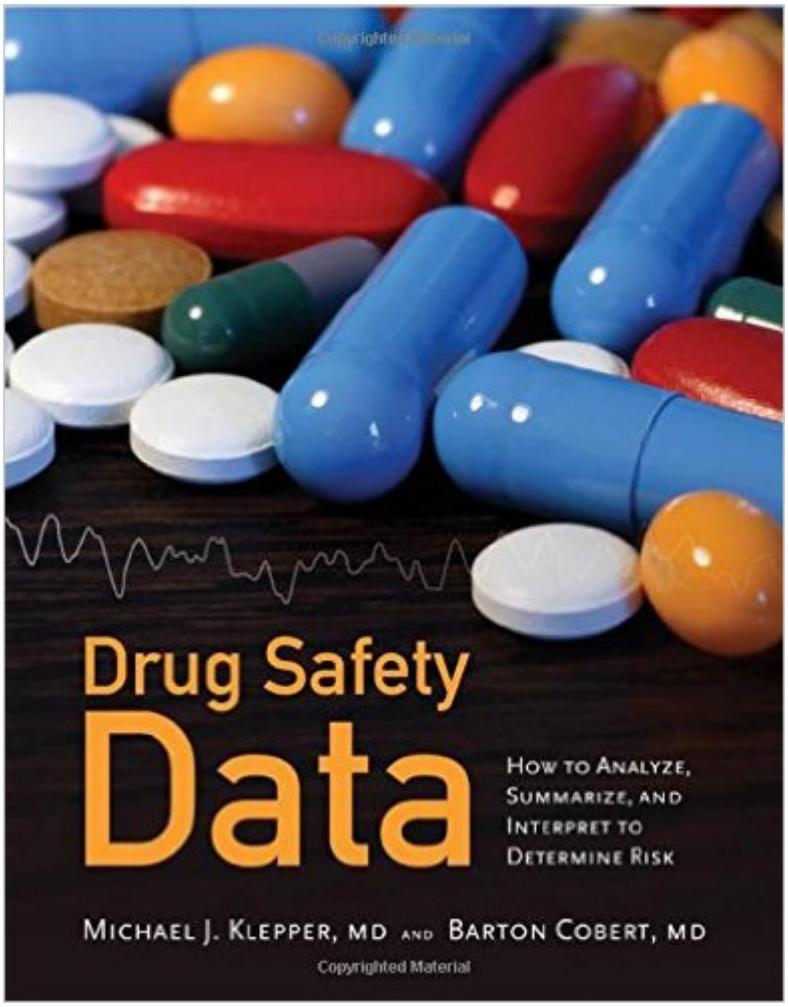
Drug Safety Data: How To Analyze, Summarize, And Interpret To Determine Risk



Synopsis

Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk was selected for The First Clinical Research Bookshelf - Essential reading for clinical research professionals by the Journal of Clinical Research Best Practices. Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk provides drug safety/pharmacovogilance professionals, pharmaceutical and clinical research scientists, statisticians, programmers, medical writers, and technicians with an accessible, practical framework for the analysis, summary and interpretation of drug safety data. The only guide of its kind, Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk is an invaluable reference for pre- and post-marketing risk assessment. With decades of pharmaceutical research and drug safety expertise, authors Dr. Klepper and Dr. Cobert discuss how quality planning, safety training, and data standardization result in significant cost, time, and resource savings. Through illustrative, step-by-step instruction, Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk is the definitive guide to drug safety data analysis and reporting. Key features include: * Step-by-step instruction on how to analyze, summarize and interpret safety data for mandatory governmental safety reports * Pragmatic tipsâ |and mistakes to avoid * Simple explanations of what safety data are collected, and what the data mean * Practical approaches to determining a drug effect and understanding its clinical significance * Guidance for determining risk throughout the lifecycle of a drug, biologic or nutraceutical * Examples of user-friendly data displays that enhance safety signal identification * Ways to improve data quality and reduce the time, resources and costs involved in mandatory safety reporting * Relevant material for the required training of drug safety/pharmacovigilance professionals * SPECIAL FEATURE: Actual examples of an Integrated Analysis of Safety (IAS) -used in the preparation of the Integrated Summary of Safety (ISS) and the Summary of Clinical Safety (SCS) reports -, and the Periodic Safety Update Report (PSUR)

Book Information

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Customer Reviews

If you are involved in or want to learn about drug safety analysis -- as clinician, statistician, writer, project manager -- this is a unique and valuable resource. It presents information logically and explains not just what but why and how. One of the best features is the in-depth sample integrated analysis of safety (IAS). This book provides an excellent understanding of benefit-risk analysis, safety profiles and more. I have worked in the pharmaceutical field for over 20 years, and I have recommended this to many people.

I’ve met one of the authors and attended one of his lectures on PV. After reviewing several of the chapters for medical writing, I found the book to be very helpful.The last chapters and appendixes are very helpful guides in developing how to writing styles for several types of reports. Not too in depth but a very good start for those who want to learn the writing style it takes to write several of these types of aggregate reports.Highly recommended as part of a drug safety professional’s library of references for both new and experienced.This is one of the few books I would definitely recommend to have as a drug safety and pharmacovigilance professional.

I’m a solo medical director in a small company needing a "crash course" on drug safety monitoring before starting a new development project. When I first thumbed through this book it seemed deceptively simple but it has provided exactly the `how to’ for pharmaceutical pharmacovigilance that I was looking for. The authors guidance on setting each component up systematically and with `the end in mind’ is straight-forward enough to implement and should be a great time saver. Inexpensive - a good buy for virtually anyone (not just MDs) who doesn’t specialize in this area of drug development.

This book is very well written. It’s chapters are well organized, and the language used is straightforward (meaning not too technical). The authors provide easy to understand definitions and they support their opinions with sound, logical rationale as well as examples. Each chapter ends

with a good, health set of citations for further reading. My background is nursing and I am fairly new to pharmacovigilance so the first set of chapters reinforce what I already know and provide rationale for processes/approaches that I have been asked to perform in my role as a drug safety specialist. I truly appreciate the examples and the narrative presented. I also respect that the authors note from time to time that "this is what we are calling it....you may call it something else, but the sentinal point is..." (paraphrasing). Each chapter is brief (a compliment to getting to the point) and presents its point(s) in a concise manner. In addition, the "voices" behind the words clearly express the importance on the patient and his/her safety. This book is a great resource to have on your shelf and/or to use with members of your organization. It is a great tool, a great resource. I believe this book is a must have.

Just what I was looking for! A concise `how to' guide written in a plain, friendly style that demystifies health authority regulations and guidelines. Although I have company SOPs to follow, this book can help me (with my nonclinical background working in Drug Safety for a pharmaceutical company) process incoming information and interpret large amounts of safety data far more intelligently. I am particularly impressed with the various examples of `real' safety compilations the authors use to illustrate theory.

industry sector - Part 3: Guidance for the determination of the required safety integrity levels Handbook of Chemical Compound Data for Process Safety (Library of Physico-Chemical Property Data) Foundations of Banking Risk: An Overview of Banking, Banking Risks, and Risk-Based Banking Regulation Modeling Risk, + DVD: Applying Monte Carlo Risk Simulation, Strategic Real Options, Stochastic Forecasting, and Portfolio Optimization Big Data, MapReduce, Hadoop, and Spark with Python: Master Big Data Analytics and Data Wrangling with MapReduce Fundamentals using Hadoop, Spark, and Python LEARN IN A DAY! DATA WAREHOUSING. Top Links and Resources for Learning Data Warehousing ONLINE and OFFLINE: Use these FREE and PAID resources to Learn Data Warehousing in little to no time The Flat World and Education: How America's Commitment to Equity Will Determine Our Future (Multicultural Education Series) The Flat World and Education: How America's Commitment to Equity Will Determine Our Future (Multicultural Education) Covering Islam: How the Media and the Experts Determine How We See the Rest of the World The Complete Guide to the Tarot: Determine Your Destiny! Predict Your Own Future!