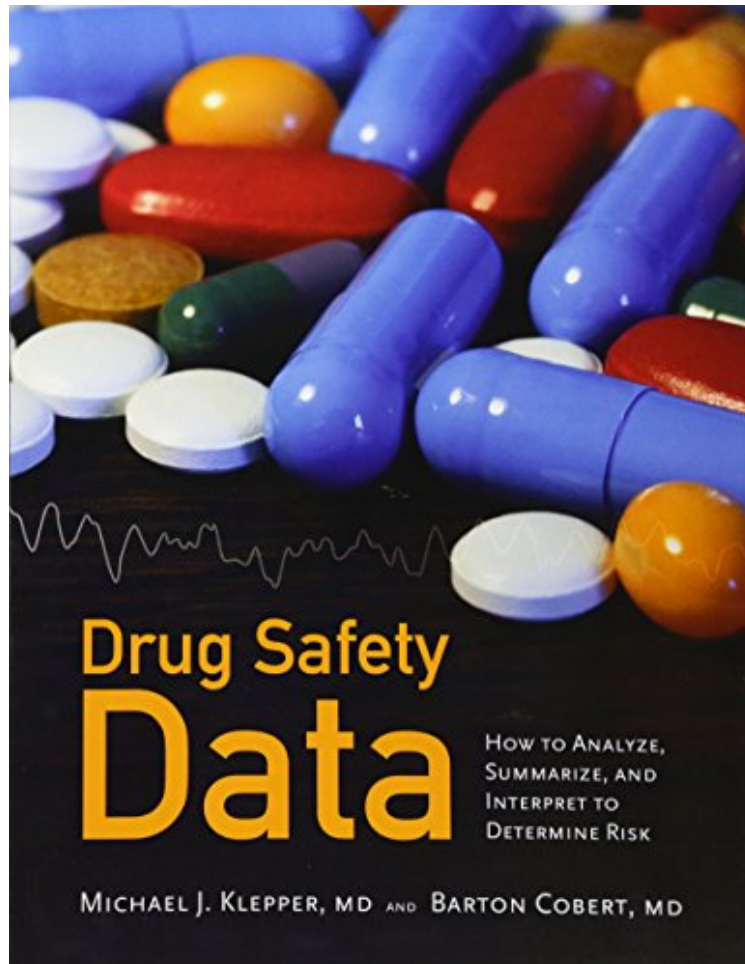


(Download) Drug Safety Data: How to Analyze, Summarize, and Interpret to Determine Risk

## Drug Safety Data: How to Analyze, Summarize, and Interpret to Determine Risk

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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.  
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Having recently taken on a new role in organizing Pharmacovigilance as well as outsourcing PV operations at a small Biotech, I found this book invaluable! It provides a very clear and realistic road map for drug safety including examples and clear guidelines for the processes required in meeting the myriad of drug safety regulations that are the reality within the Pharmaceutical/Biotech Industry. I cannot recommend this book highly enough for folks who are both new to the Industry and those with many years experience. We all have much to learn and this book has been an invaluable teacher to me despite my 20 + years of Industry experience. The key to its success is the simplicity with which it deals with and lays out the very complex world which is Pharmacovigilance.

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/pharmacovigilance 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 tips 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)