Data and Safety Monitoring Committees in Clinical Trials, Second Edition (Chapman Hall/CRC Biostatistics Series)

Jay Herson
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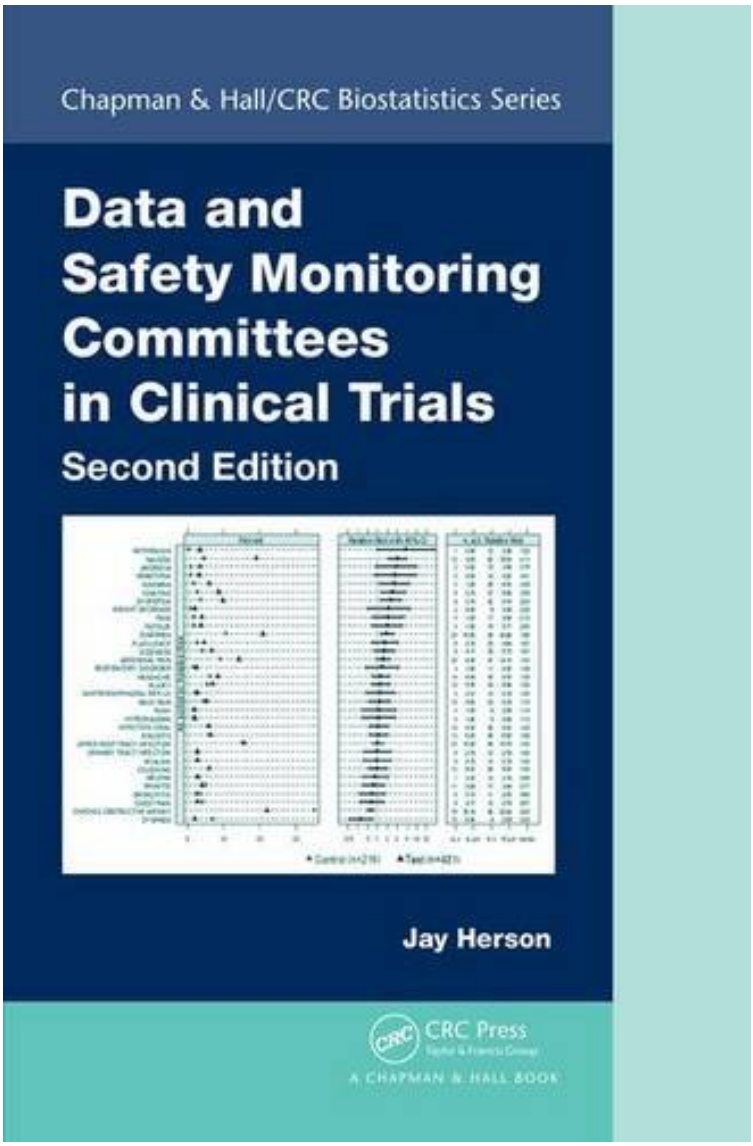

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Jay Herson : Data and Safety Monitoring Committees in Clinical Trials, Second Edition (Chapman Hall/CRC Biostatistics Series) before purchasing it in order to gage whether or not it would be worth my time, and all praised Data and Safety Monitoring Committees in Clinical Trials, Second Edition (Chapman Hall/CRC Biostatistics Series):

0 of 0 people found the following review helpful. If you want an authoritative description and explanation of Data

Monitoring Committees (DMCs), then this is the book for you.By Greg BallIf you want an authoritative description and explanation of Data Monitoring Committees (DMCs), then this is the book for you. Jay Herson has been integrally involved with DMCs since the first DMC was planned and formed in the pharmaceutical industry about 30 years ago. Still active with DMCs, he broaches the impact on DMCs by the recent FDA draft guidance for aggregate IND safety reporting. I especially appreciate the context and insight he provides on the planning, operation and philosophy of DMCs. For example, the FDA IND safety reporting final rule was designed to reduce the number of uninformative expedited safety reports and, as a result, DMCs now need to be in continuous dialog with sponsors on what AEs should be considered SUSARs. This is an important new development that requires further discussion among sponsors, DMCs and the FDA.Dr Herson provides an enlightened perspective. He recognizes that safety analyses are different from efficacy analyses and, not only does he understand the importance of objective review of accumulating data to protect patient safety, but he also understands that clinical issues and statistical issues cannot be separated. In his words, statistical methods guide the DMC in their deliberations but do not provide reasons to eliminate safety concerns from further discussion. Conversely, good medical decisionmaking requires good quantitative frameworks. Biostatisticians can work with the other DMC members to determine what statistical methods and data displays provide useful quantitative frameworks, so that, ultimately, decisions about patient safety can be driven by medical judgment. An accomplished and well-respected Biostatistician, Dr Herson certainly covers well the quantitative science of DMCs (including; meta- analyses, issues with multiplicity and benefit risk assessments), but you dont need any special training in statistics to understand what he is saying and he covers the complete life cycle of DMCs from formation to final meeting (including; organization of a safety monitoring program, clinical issues with safety data and DMC decisions).As Dr Herson says, we have seen that there is considerable subjectivity in reporting and classifying adverse events and these factors are compounded in multi-regional trials. Now more than ever, if you are involved with DMCs, if you need to separate signal from noise, you need to become familiar with this book.0 of 0 people found the following review helpful. This is an awesome book!By Weichung Joe ShihThis is an awesome book! Even though I count myself as an experienced participant in many different DSMCs for many years, I find this book fascinating, useful, and fun to read. I especially like the QA DMCounselor section at the end of each chapter based on real cases. Jay Herson writes in his unique, humorous yet informative way on serious topics. He writes so well that once start reading, you are on a journey, eager to know whats out there he is going to tell you next. The second edition is very rich, including emergent SMART, umbrella trials, and basket trials in oncology, for example. I learned a lot from this book and will recommend to my clinical trial class which I teach at Rutgers School of Public Health. It is also a great reference book for all teachers and practitioners in clinical trials.0 of 0 people found the following review helpful. A must-read for those involved with Data Monitoring Committees!By Kenneth GeraldJay Herson brings his almost 30 years experience on data monitoring committees on industry-sponsored clinical trials to this remarkable update of his 2008 book. I am particularly impressed with how clearly this book is laid out to inform the reader of the responsibilities of data monitoring committees. This book demonstrates the need for a Data Review Plan [DRP] to be drafted for DMC use. The examples of possible issues that may be encountered in a DMC makes this book an easy and interesting read. The appendix presents the aggregated lists of DRP items and DMC responsibilities. Among the new areas covered are SMART trials, umbrella/basket trials, pragmatic trials, patient reported adverse event severity, ongoing risk-benefit quantification, SUSARs and the Final Rule. There is a complete glossary and everything illustrated with references to actual clinical trials. This is a must-read for those involved with DMCs.

Praise for the first edition: "Given the authors years of experience as a statistician and as a founder of the first DMC in pharmaceutical industry trials, I highly recommend this booknot only for experts because of its cogent and organized presentation, but more importantly for young investigators who are seeking information about the logistical and philosophical aspects of a DMC." -S. T. Ounpraseuth, The American StatisticianIn the first edition of this well-regarded book, the author provided a groundbreaking and definitive guide to best practices in pharmaceutical industry data monitoring committees (DMCs). Maintaining all the material from the first edition and adding substantial new material, Data and Safety Monitoring Committees in Clinical Trials, Second Edition is ideal for training professionals to serve on their first DMC as well as for experienced clinical and biostatistical DMC members, sponsor and regulatory agency staff. The second edition guides the reader through newly emerging DMC responsibilities brought about by regulations emphasizing risk vs benefit and the emergence of risk-based monitoring. It also provides the reader with many new statistical methods, clinical trial designs and clinical terminology that have emerged since the first edition. The references have been updated and the very popular end-of-chapter QA section has been supplemented with many new experiences since the first edition.New to the Second Edition: Presents statistical methods, tables, listings and graphs appropriate for safety review, efficacy analysis and risk vs benefit analysis, SPERT and PRISMA initiatives. Newly added interim analysis for efficacy and futility section. DMC responsibilities in SUSARs (Serious Unexpected Serious Adverse Reactions), basket trials, umbrella trials, dynamic treatment strategies /SMART trials, pragmatic trials, biosimilar trials, companion diagnostics, etc. DMC responsibilities for data quality and fraud detection (Fraud Recovery Plan) Use of patient reported outcomes of safety Use of meta analysis and data outside the

trial New ideas for training and compensation of DMC membersJay Herson is Senior Associate, Biostatistics, Johns Hopkins Bloomberg School of Public Health where he teaches courses on clinical trials and drug development based on his many years experience in clinical trials in academia and the pharmaceutical industry.

About the AuthorJay Herson is Senior Associate, Biostatistics, Johns Hopkins Bloomberg School of Public Health where he teaches courses on clinical trials and drug development based on his many years experience in clinical trials in academia and the pharmaceutical industry.