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

Jay Herson
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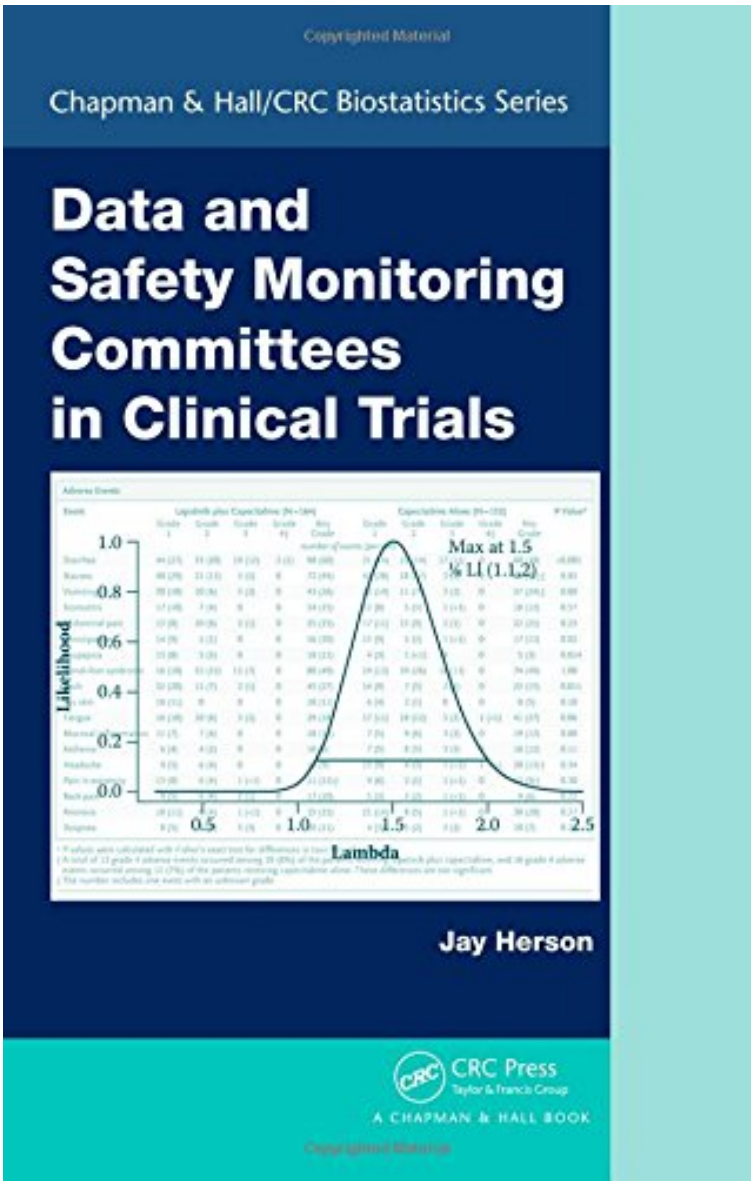

#2959679 in Books Chapman and Hall/CRC 2009-03-13Original language:EnglishPDF # 1 9.21 x .50 x 6.14l, .90 #File Name: 1420070371191 pages | File size: 48.Mb

Jay Herson : Data and Safety Monitoring Committees in Clinical Trials (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 (Chapman Hall/CRC Biostatistics Series):

0 of 0 people found the following review helpful. Three StarsBy egg loverGood read.0 of 0 people found the following review helpful. rare topic for a statistics bookBy Michael R. ChernickData and Safety Monitoring Committees place an increasingly important role as many drugs get to phase III without a thorough understanding of all the safety issues. It is the job of the committtee to ensure the safety of the trial subjects. This requires good medical knowledge and judgement. The DMC must periodically look at the trial data usually in an unblinded fashion to determine whether or not certain adverse events occur frequently enough that the risks outweigh the benefits.The book includes both the mechanics of the committee and the statistical tools used to make the interim assessment. Often group sequential stopping rules are specified by the sponsor for the DMC to use at the interim analyses. The committees have charters separate from the study protocols. Herson seems ot cover the gamut of topics with an excellent writing style.2 of 3 people found the following review helpful. Share with All Your Clinical Trial ColleaguesBy Wasima N. RidaData and safety monitoring committees (also known as data and safety monitoring boards or data monitoring committees) are important to ensure the safety and well-being of participants in clinical trials. As more and more trials utilize such committees, it is critical to educate all members of the clinical trials enterprise on the role and function of the DMC. To this end, Jay Herson has written a very useful book based on his experience monitoring trials sponsored by the pharmaceutical industry. His focus is more on the evaluation of safety than efficacy of drugs, biologics, and devices. My past experience as an FDA reviewer has taught me that assessing safety can be more challenging than assessing efficacy and so I was happy to see this emphasis. Jay provides a welcomed addition to the growing literature on DMCs. I would also recommend the book by Ellenberg, Fleming, and DeMets (2002) which gives more of a perspective from NIH sponsored trials. For the diehard statisticians, I would recommend the book by Proschan, Lan, and Wittes (2006) which dives into all the vagaries of group sequential methods for evaluating accruing safety and efficacy data.

Focusing on the practical clinical and statistical issues that arise in pharmaceutical industry trials, this book summarizes the authors experience in serving on many data monitoring committees (DMCs) and in heading up a 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.

"I found this book very useful as a clinical biostatistician with little experience with serving on a DMC. But also biostatisticians with more experience in DMCs can profit from this book since it helps in evaluating their own performance. Though the book primarily focuses on pharmaceutical industry trials, it is almost equally useful for those working on investigator-initiated trials."Theo Stijnen, ISCB News, December 2013 "This is an excellent book to stand alongside (primarily) Ellenberg et al. and (to a lesser extent) DeMets et al. an excellent book not only for those who might sit on a DMC but also for the many people who have to set up DMCs, provide reports or data to them and, very importantly, receive their recommendations and have to act on them."Simon Day, Pharmaceutical Statistics, 2011, 10 "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. As a junior statistician, I found the end-of-chapter QA section to be invaluable, because it gives a behind-the-scenes peek at DMC meetings and interactions with sponsors. the author provides virtually all relevant topics pertaining to a DMC with clarity and insight. some readers with advanced statistical background will find this text nicely complements the book by Proschan, Lan, and Wittes (2009). In summary, audiences ranging from novice clinical research practitioners to biostatisticians will find this comprehensive guide to data and safety monitoring committees a valuable addition."The American Statistician, November 2010, Vol. 64, No. 4 "Jay Herson provides a concise overview of DMCs in a useful and accessible format. For someone new to the area, this text will provide a valuable introduction quickly and effectively. At the same time, the presentation style will allow those with more knowledge to move through the material expeditiously, and they will also benefit. a valuable introduction to DMCs. an excellent overview of a complex subject. The material is presented in a very accessible format and is particularly well suited to new DMC members, or those considering such an opportunity. The material is very useful, the presentation is effective, and a strong recommendation is appropriate."Biometrics, March 2010 "When searching for books about DSMCs, you will find that Ellenburg et al. (2002) published a book with an almost identical title to Hersons. overall I would recommend Hersons book as more readable and detailed. This book would be particularly useful for anyone who becomes a DSMC member for the first time or for sponsors so that they can have a greater understanding of the DSMCs role."Andrea M. Rehman, London School of Hygiene and Tropical Medicine, Journal of the Royal Statistical Society, Series A, 2010 "This book, lively and readable and reflecting real-world experiences and lessons from DMC

safety monitoring, is a useful complement to other available texts on this subject."Paul P. Gallo, Novartis Pharmaceuticals, Journal of Biopharmaceutical Statistics, 2009, Issue 6About the AuthorJohn Hopkins University, Baltimore, Maryland, USA Pfizer Research Development, Kent, UK National Taiwan University, Taipei, Taiwan National Taiwan University, Taipei Duke University School of Medicine, Durham, North Carolina, Georgia Southern University, Statesboro, USA