



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

Jay Herson

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Focusing on the practical clinical and statistical issues that arise in pharmaceutical industry trials, this book summarizes the author's 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.

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