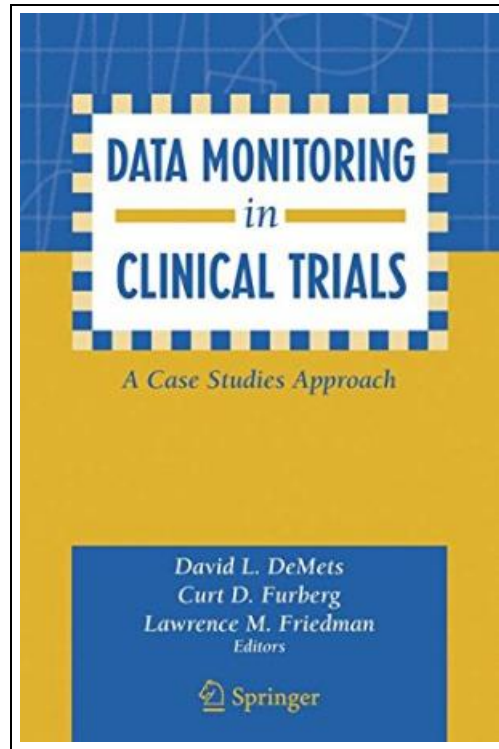


## Data Monitoring in Clinical Trials



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Springer-Verlag Gmbh Sep 2005, 2005. Taschenbuch. Condition: Neu. Neuware - Randomized clinical trials are the gold standard for establishing many clinical practice guidelines and are central to evidence based medicine. Obtaining the best evidence through clinical trials must be done within the boundaries of rigorous science and ethical principles. One fundamental principle is that trials should not continue longer than necessary to reach their objectives. Therefore, trials must be monitored for recruitment progress, quality of data, adherence to patient care or prevention standards, and early evidence of benefit or harm. Frequently, a group of external experts, independent from the investigators and trial sponsor, is charged with this monitoring responsibility, especially for safety and early benefit. This group is referred to by various names, such as a data monitoring committee or a data and safety monitoring board. This book, through a series of case studies presented by many distinguished clinical trial experts, illustrates the complexity of this monitoring process. The editors provide an overview of the process and a summary of a multitude of the lessons learned from the cases presented. This book should be useful to anyone serving on a data and safety monitoring board, or planning to do so, for colleagues in academia, industry and governmental agencies, and for teaching students in biostatistics, epidemiology, clinical trials and medical ethics. No other text has as extensive a collection of cases which provide insight into the many issues, often conflicting, that must be examined before recommendations to continue or discontinue a trial can be made. While depth in statistical methods is not required, some familiarity with statistical design and analysis issues in clinical trials is helpful. The cases cover trials which were terminated early for convincing evidence of benefit, or for harmful effects. Cases with complex issues are also included. This series...



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