



Data Monitoring in Clinical Trials

By David L. DeMets

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...



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