Data Monitoring Committees in Clinical Trials: A Practical Perspective

Susan S. Ellenberg, Thomas R. Fleming, David L. DeMets

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There has been substantial growth in the use of data monitoring committees in recent years, by both government agencies and the pharmaceutical industry. This growth has been brought about by increasing recognition of the value of such committees in safeguarding trial participants as well as protecting trial integrity and the validity of conclusions. This very timely book describes the operation of data monitoring committees, and provides an authoritative guide to their establishment, purpose and responsibilities.
* Provides a practical overview of data monitoring in clinical trials.
* Describes the purpose, responsibilities and operation of data monitoring committees.
* Provides directly applicable advice for those managing and conducting clinical trials, and those serving on data monitoring committees.
* Gives insight into clinical data monitoring to those sitting on regulatory and ethical committees.
* Discusses issues pertinent to those working in clinical trials in both the US and Europe.
The practical guidance provided by this book will be of use to professionals working in and/or managing clinical trials, in academic, government and industry settings, particularly medical statisticians, clinicians, trial co-ordinators, and those working in regulatory affairs and bioethics.

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