“Data Monitoring Committees in Clinical Trials: A Practical Perspective, 2nd edition”

Susan S. Ellenberg, Thomas R. Fleming, and David L. DeMets, 2019, 468 pages, John Wiley & Sons, $151.00

Review by Norman M. Goldfarb

“Data Monitoring Committees in Clinical Trials: A Practical Perspective, 2nd edition” is essential reading for anyone establishing, joining or interacting with data monitoring committees (DMCs), also known as data and safety monitoring boards (DSMBs).

While everyone else waits anxiously for the results of a clinical study, the DSMB can pore over the data to determine whether a study’s interim results indicate that the study protocol should be revised or the study stopped early because of a safety issue, because further data is unnecessary to prove or reject the study hypothesis, or because further data is unlikely to prove or reject the hypothesis.

The book looks at the practicalities of DMCs from every angle. For example, the following excerpt addresses one scenario that might justify sharing blinded safety data with appropriate members of the study team:

Settings and procedures allowing broader unblinding of safety data

As with efficacy data, comparative data on safety in general should not be released prematurely to the sponsor or to others who are not DMC members. While the relative safety data can be quite extensive, even in the early stages of a trial when efficacy data are still sparse, it is usually not possible to make reliable assessments of the relative benefit-to-risk profiles on the basis of early safety data. Release of such data could compromise the trial’s ability to obtain the longer-term efficacy and safety data required for reliable assessments about the true benefit-to-risk profiles of the treatments under study.

At times, the DMC may consider allowing broader access to safety data during the conduct of the study. It is appropriate to provide early access to unexpected adverse events that are serious and plausibly treatment related. This is particularly important when such release would guide decisions about refinements in the dosing/schedule of a study regimen or in the selection criteria for the trial in order to substantially reduce the risk of that adverse effect. In such circumstances, the DMC will have to balance potential risks to patients if information is not released with the potential risk to the study integrity if it is.

The book includes 11 chapters:

- Introduction
- Responsibilities of the Data Monitoring Committee and Motivating Illustrations
- Composition of a Data Monitoring Committee
- Independence of the Data Monitoring Committee: Avoiding Conflicts of Interest
- Confidentiality Issues Relating to the Data Monitoring Committee

This book has been selected for The First Clinical Research Bookshelf
Essential reading for clinical research professionals
• Data Monitoring Committee Meetings
• Data Monitoring Committee Interactions with Other Trial Components or Related Groups
• Statistical, Philosophical and Ethical Issues in Data Monitoring
• Determining When a Data Monitoring Committee is Needed
• Regulatory Considerations for the Operation of Data Monitoring Committees
• Legal Considerations for DMCs

Reviewer

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