JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 3, No. 9, September 2007 "Can You Handle the Truth?"

"Data Monitoring Committees in Clinical Trials: A Practical Perspective"

Susan S. Ellenberg, Thomas R. Fleming, and David L. DeMets, 2003, 191 pages, John Wiley & Sons, $130.00

Review by Norman M. Goldfarb

"Data Monitoring Committees in Clinical Trials: A Practical Perspective" is essential reading for anyone establishing, joining or interacting with data monitoring committees (DMCs), also known as data and safety monitoring boards (DSMBs). The book looks at the practicalities of DMCs from every angle, including:

- Responsibilities
- Composition
- Independence
- Conflict of interest
- Confidentiality
- Committee meetings
- Interactions with other groups
- Statistical, philosophical and ethical issues
- When a data monitoring committee is needed
- Regulatory considerations

This book has been selected for

The First Clinical Research Bookshelf

Essential reading for clinical research professionals

DMCs are granted access to unblinded interim study data to ensure that the study remains safe and is likely to yield useful results. If a DMC sees a potential problem, it can recommend midcourse corrections such as changes to the protocol, or early termination of the study. DMCs do not just stop studies; the book includes real-life examples in which DMC recommendations rescued studies that would have been useless if continued without change. With DMC advocacy, other studies have continued to a successful conclusion despite apparent problems in the interim blinded data.

The book covers the topic in detail. For example, DMC members may encounter perplexing situations related to confidentiality. For example, if the interim data is tending strongly in favor of a treatment that is not standard-of-care, and the member has patients with the study condition, should the member modify his/her patients' therapy? What if the member has the condition him/herself?

The book is available at bookstores.

Reviewer

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