

"How to Create & Structure a Data Monitoring Committee"

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Review by Norman M. Goldfarb

"How to Create & Structure a Data Monitoring Committee" provides useful perspectives and advice for data monitoring committees (DMCs). A 15-page essay discusses the history of data monitoring committees, key features of FDA's 2006 Guidance, and tips for implementation.

A data monitoring committee – the term used by the FDA rather than, for example, data and safety monitoring committee – is a standard feature in large, randomized, high-risk trials, and spreading into other trials as well. To maximize DMC benefits, there should be formal policies and procedures that minimize problems with independence, confidentiality and inattentive members. In particular, there should be a policy for handling the sticky situation when the DMC makes a recommendation and the study sponsor does not agree with it. To reduce the temptation for non-members to fish for information, sponsors may want to conceal the identity of DMC members, or at least keep them physically separate from the study team.

FDA guidance allows a broad view of the DMC charter, including review of informed consent and case report forms. However, the essay cautions that DMCs should avoid diluting focus on their primary mission: reviewing interim data to advise sponsors on subject safety and the validity and scientific merit of the study. Independent DMCs provide an important defense in subject injury litigation because the sponsor can correctly claim that it did not know the interim status of the study. As adaptive trials become more common, the importance of DMCs will increase because they are the only oversight body with access to the unblinded data needed to make some adaptation decisions.

The essay is accompanied by the FDA Guidance and eight other relevant government documents.

The report is available at <http://www.fdanews.com>

Reviewer

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