adverse drug reactions. It is much better to exclude one particular subgroup from the clinical trial than to terminate the entire clinical trial.

Along similar lines, the DMC may recommend increased surveillance of specific adverse events, where the DMC suspects that a certain type of adverse event is not being adequately detected (249).

The FDA's Establishment and Operation of Clinical Trial Data Monitoring Committees provides a brief introduction to the DMC's structure and functions (250). DeMets et al. (251) have written an indispensable account of the activities of Data and Safety Monitoring Committees.

## a. The DMC Charter

The responsibilities of the Data and Safety Monitoring Committee are formally set forth in a DMC Charter (or DSMC Charter). The DMC Charter, which can be written by a medical writer, is tailored to the needs of the clinical trial. The Charter can provide a schedule of meetings used for interim analysis. The meetings may be scheduled according to calendar dates, or in a manner that tracks the number of patients being enrolled as the trial unfolds. If the clinical trial has stopping rules, the Charter provides the statistical bases for stopping for benefit, stopping for safety, and stopping for futility. The following is a draft of a DMC Charter, based on a composite of the author's own work, in combination with a published DMC Charter (252). The name of the company, *PharmaDrug*, *Inc.*, is fictional.

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**Data Safety Monitoring Board Charter**

Clinical Study Protocol No.: _____

_____ _____
_____, MD Signature Date
(DMC chairperson)

_____ _____
_____, MD, MPH Signature Date
(DMC member)

_____ _____
_____, PhD Signature Date
(DMC biostatistician)

[249] Grant AM, Altman, DG, Babiker AB, et al. Issues in data monitoring and interim analysis of trials. *Health Technol Assess*. 2005;9(7) [246 pages].

[250] U.S. Dept. of Health and Human Services. Food and Drug Administration. Guidance for Clinical Trial Sponsors. Establishment and Operation of Clinical Trial Data Monitoring Committees (March 2006).

[251] DeMets DL, Furberg CD, Friedman LM. *Data Monitoring in Clinical Trials*. New York, NY: Springer; 2006.

[252] Data Monitoring Committee (DMC) Charter for the Eurother3235 Trial (version 1.0 27/04/2009).