

subjective responses, such as pain, fatigue, nausea, or depression.

XXI. DATA AND SAFETY MONITORING COMMITTEE

a. Introduction

The Data and Safety Monitoring Committee (DSMC), also known as a Data Monitoring Committee (DMC), is a group of about six people, appointed by the sponsor or investigator, that serves as an independent monitor of the clinical trial, as it progresses. DMCs are not used in all clinical trials, but are strongly recommended for trials where one of the endpoints is death, trials for life-threatening diseases, and trials with huge numbers of study subjects (400). Use of DMCs in clinical trials had an origin in the Greenberg Report (401).

What is monitored is data on safety, data on efficacy, and adherence to the terms in the Clinical Study Protocol, as the clinical study unfolds and progresses. Members of the DMC include an expert in the disease being studied,

an expert in the design of clinical trials, a statistician, and an expert in medical ethics. The members of the DMC must not be affiliated with the sponsor, investigator, for example, a pharmaceutical company, or with a competing pharmaceutical company. The primary goal of the DMC is to protect the safety of the study subjects, in the context of a clinical trial on an experimental drug (402). The DMC has the power to unblind the study subjects, and determine whether any given data point is from a subject receiving placebo or study drug. Two reports are often prepared by the DMC, one for the open session and one for the closed session (403). The open session report may be a subset of the closed session report or entirely separate.

The DMC meets at regular intervals, for example, every 6 months, to review the available data. This analysis is called “interim analysis,” whereas analysis performed at the conclusion of the clinical trial is called “final analysis” (404,405). Once the clinical trial is underway, the DMC can recommend stopping the trial because of benefit (406,407), safety, or futility (408). The meaning of these three

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