IX. SUMMARY OF REPORTING SYSTEMS SUITABLE FOR CAPTURING ADVERSE EVENTS

To view the big picture, adverse event data can be reported by the following four systems:

- As adverse events, using the MedDRA dictionary, where data are collected by the clinician;
- As adverse events, using the CTCAE dictionary, where data from oncology clinical trials are collected by the clinician;
- As patient-reported outcomes (PROs), where data are collected by an instrument filled out by the patient; and
- As HRQoL instruments, where data are also collected by an instrument filled out by the patient. HRQoL instruments are detailed in a separate chapter in this book.

An investigator would not indiscriminately use all of these methods for capturing safety data, in view of the burden and expense involved (239). The instruments that are chosen will be a function of whether the study drug has any relevance to the patient's subjective responses, such as pain, fatigue, nausea, or depression.

X. DATA AND SAFETY MONITORING COMMITTEE

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 (240). Use of DMCs in clinical trials had an origin in the Greenberg Report (241).

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 (242). The DMC has the power to unblind the study subjects,

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