A clinical trial is designed to answer a primary question, with a pre-specified analysis of the primary endpoint. Upon completion of a trial, full information is available to answer the question. For clinical trials in which data accrue before completion, issues arise that are unique to interim reporting. Data monitoring committees (DMCs) need to be aware of these issues and how they affect endpoint validity. A typical endpoint may be mortality, a disease-related event such as stroke, or a composite endpoint. In many trials, outcomes should be adjudicated; that is, clinicians must judge whether an event reported by trial investigators during a trial. During a trial not all events have been adjudicated; thus, "unadjudicated" or best-available information must be used for analyses, resulting in adjudication results with reported events.

Interim clinical trial data can be missing, inconsistent, or incomplete. Procedures are needed to handle this type of data. For example, data may be missing for time-to-event analyses; and other analysis concerns. We discuss some of our best practices for handling missing data in the following sections.

For More Information…

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