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Autore	Ellenberg Susan Smith
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2.2.3.5 Consideration of the overall picture: primary and secondary analyses
2.2.3.6 Modifying sample sizes based on ongoing assessment of event rates 2.2.4 Reviewing the final results; 2.3 The data monitoring committee charter; References; 3 Composition of a data monitoring committee; 3.1 Introduction; 3.2 Required areas of expertise; 3.3 Other relevant characteristics of committee members; 3.4 Committee size; 3.5 Selecting the committee chair; 3.6 Responsibility for appointing committee members; 3.7 Representation of other study components on the committee; 3.8 Preparation for service on a committee; References 4 Independence of the data monitoring committee: avoiding conflicts of interest 4.1 Introduction; 4.2 Rationale for independence; 4.3 Financial independence; 4.3.1 Sponsors; 4.3.2 Academic investigators; 4.4 Intellectual independence; 4.5 Emotional conflicts; 4.6 Individuals without conflicts; References; 5 Confidentiality issues relating to the data monitoring committee; 5.1 Rationale; 5.2 Limits of confidentiality; 5.2.1 Interim analysis reports; 5.2.2 Access to aggregate data on efficacy and safety outcomes; 5.2.3 The steering committee and maintaining confidentiality
5.2.4 Settings and procedures allowing broader unblinding 5.2.5 Some illustrations of broader unblinding; 5.2.6 Indirect challenges to confidentiality; 5.3 The need for the data monitoring committee to review unblinded data; References; 6 Data monitoring committee meetings; 6.1 Introduction; 6.2 Specific objectives and timing of meetings; 6.2.1 Organizational meeting; 6.2.2 Early safety/trial integrity reviews; 6.2.3 Formal interim efficacy analyses; 6.2.4 End-of-trial debriefing; 6.3 Preparation of meeting reports; 6.4 Format for meetings; 6.4.1 The closed session; 6.4.2 The open session
6.4.3 The final closed session

Sommario/riassunto

There has been substantial growth in the use of data monitoring committees in recent years, by both government agencies and the pharmaceutical industry. This growth has been brought about by increasing recognition of the value of such committees in safeguarding trial participants as well as protecting trial integrity and the validity of conclusions. This very timely book describes the operation of data monitoring committees, and provides an authoritative guide to their establishment, purpose and responsibilities.* Provides a practical overview of data monitoring in clinical trials.*