1. Record Nr. UNINA9910689552203321

Titolo	The American Travel Promotion Act : hearing before the Subcommittee on Commerce, Trade, and Consumer Protection, Committee on Energy and Commerce, House of Representatives, One Hundred Seventh Congress, second session on H.R. 3321, May 23, 2002
Descrizione fisica	1 online resource (iii, 42 p.)
Soggetti	Tourism - Law and legislation - United States Tourism - Government policy - United States
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia

2. Record Nr. UNINA9911018808403321

Autore	Ellenberg Susan Smith
Titolo	Data monitoring committees in clinical trials : a practical perspective / / Susan S. Ellenberg, Thomas R. Fleming, David L. DeMets
Pubbl/distr/stampa	Chichester ; ; Hoboken, NJ, : Wiley, c2002
ISBN	9786610269990 9781280269998 1280269995 9780470322284 0470322284 9780470854150 0470854154 9780470854167 0470854162
Descrizione fisica	1 online resource (209 p.)
Collana	Statistics in practice
Altri autori (Persone)	FlemingThomas R DeMetsDavid L. <1944->
Disciplina	610/.72/4 615.190072
Soggetti	Clinical trials Medical ethics committees
Lingua di pubblicazione	Inglese

Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Data Monitoring Committees in Clinical Trials A Practical Perspective; Contents; Preface; 1 Introduction; 1.1 Motivation; 1.2 History of data monitoring committees in government-sponsored trials; 1.3 Data monitoring committees in trials sponsored by the pharmaceutical industry; 1.4 Statistical methods for interim monitoring; 1.5 When are data monitoring committees needed?; 1.6 Where we are today; 1.7 Fundamental principles of data monitoring; References; 2 Responsibilities of the data monitoring committee and motivating illustrations; 2.1 Fundamental charges 2.2 Specific tasks of the data monitoring committee 2.2.1 Initial review; 2.2.1.1 Review of the study protocol; 2.2.1.2 Review of procedures to ensure quality of study conduct; 2.2.2 Evaluating the quality of ongoing study conduct; 2.2.3 Assessing safety and efficacy data; 2.2.3.1 Termination due to favorable benefit-to-risk; 2.2.3.2 Termination due to unfavorable benefit-to-risk; 2.2.3.3 Termination due to inability to answer trial questions; 2.2.3.4 Continuation of ongoing clinical trials; 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.*