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Edizione	[Second edition.]
Descrizione fisica	1 online resource (493 pages)
Collana	Statistics in practice
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Note generali	Preceded by Data monitoring in committees in clinical trials : a practical perspective / Susan S. Ellenberg, Thomas R. Fleming, David L. DeMets. 2002.
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Responsibilities of the data monitoring committee and motivating illustrations -- Composition of a data monitoring committee -- Independence of the data monitoring committee : avoiding conflicts of interest -- Confidentiality issues relating to the data monitoring committee -- Data monitoring committee meetings -- Data monitoring committee interactions with other trial components or related groups -- Statistical, philosophical and ethical issues in data monitoring -- Determining when a data monitoring committee is needed -- Regulatory considerations for the operation of data monitoring committees -- Legal considerations for DMCs.
Sommario/riassunto	The authoritative guide for Data Monitoring Committees--fully revised and updated The number of clinical trials sponsored by government agencies and pharmaceutical companies has grown in recent years, prompting an increased need for interim monitoring of data on safety and efficacy. Data Monitoring Committees (DMCs) are an essential component of many clinical trials, safeguarding trial participants and protecting the credibility and validity of the study. Data Monitoring Committees in Clinical Trials: A Practical Perspective, 2nd Edition offers practical advice for those managing and conducting clinical trials and

serving on Data Monitoring Committees, providing a practical overview of the establishment, purpose, and responsibilities of these committees. Examination of topics such as the composition and independence of DMCs, statistical, philosophical and ethical considerations, and determining when a DMC is needed, presents readers with a comprehensive foundational knowledge of clinical trial oversight. Providing recent examples to illustrate DMC principles, this fully-updated guide reflects current developments and practices in clinical trial oversight and offers expanded coverage of emerging issues and challenges in the field. This new second edition covers the most current information on DMC policies, issues in monitoring trials using new designs, and recent trial publications relevant to DMC decision-making. * Presents practical advice for those managing and conducting clinical trials and serving on Data Monitoring Committees * Illustrates the types of challenging issues Data Monitoring Committees face in practical situations * Provides updated and expanded coverage of topics including regulatory and funding agency guidelines and trial designs and their associated demands and limitations * Includes a new chapter addressing legal issues that affect DMC members and discusses general litigation concerns relevant to clinical research * Expands treatment of current journal publications addressing DMC issues Data Monitoring Committees in Clinical Trials: A Practical Perspective, 2nd Edition is a must-have text for anyone engaged in DMC activities as well as trial sponsors, clinical trial researchers, regulatory and bioethics professionals, and those associated with clinical trials in academic, government and industry settings.