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Nota di contenuto	Introduction-.What is a DMC?-. Is a DMC required?-. Who is On the DMC?-. What are the Legal and Ethical Aspects of DMC?-. How does the DMC work with SDAC and Sponsor and External Groups ? -- What Does a DMC Meeting Look Like -- What data is used for DMC outputs and who programs? -- What is Included in DMC Outputs? -- What does the DMC final DMC outputs look like and how is it delivered? -- What Types of Safety Outputs Does the DMC Receive? -- What types of efficacy outputs does the DMC receive? -- What types of other outputs does the DMC receive? -- What About In-Between DMC Meetings -- What types

of formal interim analyses does the DMC review? -- What does the paperwork from meetings look like? -- How does the DMC assess risk-benefit for their decision making? -- What are some examples? -- Conclusions.

Sommario/riassunto

This book provides an overview of Data Monitoring Committees - what was done in the past, what is currently being done, and thoughts on improvements for the future. Previous works focused primarily on large cardiovascular studies (where DMCs originated more than 30 years ago) but updated references are needed that discuss smaller, more flexible studies in areas such as oncology. The authors have attended ~800 DMC meetings from ~200 distinct studies across all areas of clinical studies (oncology, rheumatology, rare diseases, cardiology, immunology, etc.) This wide range of expertise will be used, as well as the expertise that comes from working with virtually every large biotech/pharma and CRO for DMC work. The reader of the book will know when DMCs are needed or helpful, how to form the DMC, how to work with external CROs and with sponsor teams and the DMC to create needed DMC outputs, how the DMC meetings are conducted, and - especially for DMC members - what are considerations within the Closed Session to review safety/efficacy outputs to assess risk/benefit to make appropriate recommendations that protect the patient safety and trial integrity. This is a practical hands-on book on how to decide if a DMC is necessary, how to form the DMC, how to smoothly create the necessary materials for the DMC and have smooth running DMC meetings. There is no specialized training in school about how DMCs work - frequently people may have been in industry for many years without ever needing to work with a DMC. This book is the helpful reference for those new to these DMCs. The DMC work is critical to be correctly implemented as the implications of it are so great. This book provides the following: Thorough instructions on the steps needed to form and implement a Data Monitoring Committee for clinical trial evaluation; Includes practical and hands-on information on DMC implementation; Discusses a wide range ofclinical trial – by phase and therapeutic area.