

# **Data Monitoring In Clinical Trials**

**Michelle Denise Roth-Cline** 

## **Data Monitoring In Clinical Trials:**

Data Monitoring in Clinical Trials David L. DeMets, Curt D. Furberg, Lawrence M. Friedman, 2006-06-22 Randomized clinical trials are the gold standard for establishing many clinical practice guidelines and are central to evidence based medicine Obtaining the best evidence through clinical trials must be done within the boundaries of rigorous science and ethical principles One fundamental principle is that trials should not continue longer than necessary to reach their objectives Therefore trials must be monitored for recruitment progress quality of data adherence to patient care or prevention standards and early evidence of benefit or harm Frequently a group of external experts independent from the investigators and trial sponsor is charged with this monitoring responsibility especially for safety and early benefit This group is referred to by various names such as a data monitoring committee or a data and safety monitoring board This book through a series of case studies presented by many distinguished clinical trial experts illustrates the complexity of this monitoring process The editors provide an overview of the process and a summary of a multitude of the lessons learned from the cases presented This book should be useful to anyone serving on a data and safety monitoring board or planning to do so for colleagues in academia industry and governmental agencies and for teaching students in biostatistics epidemiology clinical trials and medical ethics No other text has as extensive a collection of cases which provide insight into the many issues often conflicting that must be examined before recommendations to continue or discontinue a trial can be made While depth in statistical methods is not required some familiarity with statistical design and analysis issues in clinical trials is helpful The cases cover trials which were terminated early for convincing evidence of benefit or for harmful effects Cases with complex issues are also included This series of cases should provide broad background information for potentialmonitoring committee members and better prepare them for the challenges that may exist in the trials for which they are responsible This book is a must read for individuals serving on or supporting data monitoring committees as well as statisticians and other disciplines involved in the design and analysis of clinical trials with interim monitoring Journal of Biopharmaceutical Sciences Issue 6 2006 Data Monitoring Committees in Clinical Trials Susan S. Ellenberg, Thomas R. Fleming, David L. DeMets, 2019-01-14 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 Data and Safety Monitoring Committees in Clinical Trials Jay Herson, 2009-03-13 Focusing on the practical clinical and statistical issues that arise in pharmaceutical industry trials this book summarizes the author's experience in serving on many data monitoring committees DMCs and in heading up a contract research organization that provided statistical support to nearly seventy five DMCs It explains the difference in DMC operations between the pharmaceutical industry and National Institutes of Health NIH sponsored trials Leading you through the types of reports for adverse events and lab values the author presents the statistical requirements of data monitoring committees and gives advice on how statisticians can best interact with physician members of these committees He also shows how physicians think differently about safety data than statisticians proving that both views are needed Monitoring of Clinical Trials Lemuel A. Moyé, 2006-02-28 Statistical Monitoring of Clinical Trials Fundamentals for Investigators introduces the investigator and statistician to monitoring procedures in clinical research Clearly presenting the necessary background with limited use of mathematics this book increases the knowledge experience and intuition of investigations in the use of these important procedures now required by the many clinical research efforts. The author provides motivated clinical investigators the background correct use and interpretation of these monitoring procedures at an elementary statistical level He defines terms commonly used such as group sequential procedures and stochastic curtailment in non mathematical language and discusses the commonly used procedures of Pocock O Brien Fleming and Lan DeMets He discusses the notions of conditional power monitoring for safety and futility and monitoring multiple endpoints in the study The use of monitoring clinical trials is introduced in the context of the evolution of clinical research and one chapter is devoted to the more recent Bayesian procedures From the reviews The author has a wealth of experience in this area and this is demonstrated throughout the text with relevant poignant examples Short Book Reviews of the ISI June 2006 Data

and Safety Monitoring in Clinical Trials Michelle Denise Roth-Cline, 2006 Data Monitoring Committees in Clinical Trials Susan S. Ellenberg, Thomas R. Fleming, David L. DeMets, 2019-04-01 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 quide 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 Proceedings of practical issues in data monitoring of clinical trials Susan S. Ellenberg,1993 Management of Data in Clinical Trials Eleanor McFadden, 2007-07-30 A valuable new edition of the trusted practical guide to managing data in clinical trials Regardless of size type or complexity accurate results for any clinical trial are ultimately determined by the quality of the collected data Management of Data in Clinical Trials Second Edition explores data management and trial organization as the keys to developing an accurate and reliable clinical trial With a focus on the traditional aspects of data collection as well as recent advances in technology this new edition provides a complete and accessible guide to the management structure of a clinical trial from planning and development to design and analysis Practical approaches that result in the collection of complete and timely data are also provided While maintaining a comprehensive overview of the knowledge and tools that are essential for the organization of a modern clinical trial the author has expanded the topical coverage in the Second Edition to reflect the

possible uses of recent advances in technology in the data collection process In addition the Second Edition discusses the impact of international regulations governing the conduct of clinical trials and provides guidelines on ensuring compliance with national requirements Newly featured topics include The growing availability of off the shelf solutions for clinical trials Potential models for collaboration in the conduct of clinical trials between academia and the pharmaceutical industry The increasing use of the Internet in the collection of data and management of trials Regulatory requirements worldwide and compliance with the ICH Good Clinical Practice GCP Guidelines Development of Standard Operating Procedures for the conduct of clinical trials Complete with chapter summaries that reinforce key points as well as over one hundred examples Management of Data in Clinical Trials Second Edition is an ideal resource for practitioners in the clinical research community who are involved in the development of clinical trials including data managers research associates data coordinators physicians and statisticians This book also serves as an excellent supplemental text for courses in clinical trials at both the undergraduate and graduate levels Data Monitoring in Clinical Trials and the Ethics of Human **Experiemntation** James F. Ward, 2001 Fundamentals of Clinical Trials Lawrence M. Friedman, Curt D. Furberg, David L. DeMets, David M. Reboussin, Christopher B. Granger, 2015-08-27 This is the fifth edition of a very successful textbook on clinical trials methodology written by recognized leaders who have long and extensive experience in all areas of clinical trials The three authors of the first four editions have been joined by two others who add great expertise A chapter on regulatory issues has been included and the chapter on data monitoring has been split into two and expanded Many contemporary clinical trial examples have been added There is much new material on adverse events adherence issues in analysis electronic data data sharing and international trials This book is intended for the clinical researcher who is interested in designing a clinical trial and developing a protocol It is also of value to researchers and practitioners who must critically evaluate the literature of published clinical trials and assess the merits of each trial and the implications for the care and treatment of patients The authors use numerous examples of published clinical trials to illustrate the fundamentals The text is organized sequentially from defining the question to trial closeout One chapter is devoted to each of the critical areas to aid the clinical trial researcher. These areas include pre specifying the scientific questions to be tested and appropriate outcome measures determining the organizational structure estimating an adequate sample size specifying the randomization procedure implementing the intervention and visit schedules for participant evaluation establishing an interim data and safety monitoring plan detailing the final analysis plan and reporting the trial results according to the pre specified objectives Although a basic introductory statistics course is helpful in maximizing the benefit of this book a researcher or practitioner with limited statistical background would still find most if not all the chapters understandable and helpful While the technical material has been kept to aminimum the statistician may still find the principles and fundamentals presented in this text useful The Data Safety Monitoring Board - Module A Kalman Dubov, 2022-01-09 A key function during clinical trials

is the Data Safety Monitoring Board DSMB The board is composed of several experts who review the investigational trial and receive unblinded data from the clinical investigator as well as the study sponsor The unblinded data can be reviewed to determine if an adverse event is relevant to the study The DSMB has the authority if necessary to stop the study at an appropriate juncture There are two modules that present the concept of the DSMB with specific detail related to investigational studies where the establishment of the DSMB is warranted The key factor of reviewing an adverse event at an investigational site allows the DSMB to assess the risks in the study The DSMB is established by charter detailing the scope of the board s authority the composition of its members how often the board will meet and the types of meetings the board will conduct In addition the board must be grounded in the design types of studies so they are appreciative of the way the investigational trial will be conducted Module B continues with different phases of clinical trials with a key discussion of the study types where a DSMB is mandated the board must also be aware of the FDA s recall system since it may affect the ongoing investigational trial The review continues with the types of meetings undertaken by the DSMB to include information obtained from the Department of Defense Research Monitor who may be a DSMB voting member The module then reviews the specific actions the DSMB may take during the study with practical recommendations the board should consider during its meetings A critical aspect of the board's responsibility is its communication with the institutional review board IRB whether a specific IRB or a multiplicity of different IRBs While the IRB does not receive unblinded data the DSMB only receives unblinded data so that communication with the IRB by necessity is restricted to data that can be shared with the IRB However if the DSMB stops a study the IRB must be notified immediately so that the study s approval can be withdrawn The scope of the duties of the DSMB is to provide the members with key data so as to protect the study subjects and ensure the Ellenberg, National Institute of Allergy and Infectious Diseases (U.S.), National Heart, Lung, and Blood Institute, National The Data Safety Monitoring Board - Module B Kalman Dubov, A key function during clinical Cancer Institute (U.S.), 1993 trials is the Data Safety Monitoring Board DSMB The board is composed of several experts who review the investigational trial and receive unblinded data from the clinical investigator as well as the study sponsor The unblinded data can be reviewed to determine if an adverse event is relevant to the study The DSMB has the authority if necessary to stop the study at an appropriate juncture There are two modules that present the concept of the DSMB with specific detail related to investigational studies where the establishment of the DSMB is warranted The key factor of reviewing an adverse event at an investigational site allows the DSMB to assess the risks in the study The DSMB is established by charter detailing the scope of the board's authority the composition of its members how often the board will meet and the types of meetings the board will conduct In addition the board must be grounded in the design types of studies so they are appreciative of the way the investigational trial will be conducted Module B continues with different phases of clinical trials with a key discussion of the

study types where a DSMB is mandated the board must also be aware of the FDA s recall system since it may affect the ongoing investigational trial The review continues with the types of meetings undertaken by the DSMB to include information obtained from the Department of Defense Research Monitor who may be a DSMB voting member The module then reviews the specific actions the DSMB may take during the study with practical recommendations the board should consider during its meetings A critical aspect of the board's responsibility is its communication with the institutional review board IRB whether a specific IRB or a multiplicity of different IRBs While the IRB does not receive unblinded data the DSMB only receives unblinded data so that communication with the IRB by necessity is restricted to data that can be shared with the IRB However if the DSMB stops a study the IRB must be notified immediately so that the study s approval can be withdrawn The scope of the duties of the DSMB is to provide the members with key data so as to protect the study subjects and ensure the trial is conducted in an optimal manner Clinical Research Monitoring: A European Approach A A Van Dooren, 2017-09-21 Clinical research monitoring is a vital aspect of Good Clinical Practice GCP Its principles are straightforward they are aimed at protecting those subjects that participate in the trial and their goal is to provide reliable data that will contribute to the safety and efficacy of the intervention under study i e to support the health of future subjects However the practical implementation of these major goals is complicated Various mishaps have happened in recent history and an extensive set of international rules and regulations have emerged This book gives a thorough survey of the ethical and legal aspects of clinical research and provides a detailed guideline for implementing these aspects into the practice of studying investigational medicinal products in humans in the European context It can be used as a study aid for starting monitors a reference guide for more experienced monitors and anyone else involved in clinical research Related Link's Risk-Based Monitoring and Fraud Detection in Clinical Trials Using JMP and SAS Richard C. Zink, 2014-07 International guidelines recommend that clinical trial data should be actively reviewed or monitored the well being of trial participants and the validity and integrity of the final analysis results are at stake Risk based monitoring RBM makes use of central computerized review of clinical trial data and site metrics to determine if and when clinical sites should receive more extensive quality review or intervention Risk Based Monitoring and Fraud Detection in Clinical Trials Using JMP and SAS describes analyses for RBM that incorporate and extend the recommendations of TransCelerate Biopharm Inc methods to detect potential patient or investigator misconduct snapshot comparisons to more easily identify new or modified data and other novel visual and analytical techniques to enhance safety and quality reviews The analytical methods described enable the clinical trial team to take a proactive approach to data quality and safety to streamline clinical development activities and address shortcomings while the study is ongoing **Data Monitoring Committees (DMCs)** Nand Kishore Rawat, David Kerr, 2023-06-08 This book provides an overview of Data Monitoring Committees DMC 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 biotechnology and pharmaceutical company 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 expertly 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 impact of DMC activity on safeguarding the trial is so important This book provides the following Provides 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 of clinical trial by phase and therapeutic area Issues in Data Monitoring of Clinical Trials ,1993 A Practical Guide to Managing Clinical Trials JoAnn Pfeiffer, Cris Wells, 2017-05-18 A Practical Guide to Managing Clinical Trials is a basic comprehensive guide to conducting clinical trials Designed for individuals working in research site operations this user friendly reference guides the reader through each step of the clinical trial process from site selection to site set up subject recruitment study visits and to study close out Topics include staff roles responsibilities training budget and contract review and management subject study visits data and document management event reporting research ethics audits and inspections consent processes IRB FDA regulations and good clinical practices Each chapter concludes with a review of key points and knowledge application Unique to this book is A View from India a chapter by chapter comparison of clinical trial practices in India versus the U S Throughout the book and in Chapter 10 readers will glimpse some of the challenges and opportunities in the emerging and growing market of Indian clinical trials Clinical Trials in Cardiovascular Disease Charles H. Hennekens, 1999 Here's a companion to the well respected and popular HEART DISEASE 5th Edition by Braunwald Expertly edited this text offers an assessment of treatments for cardiovascular disease and provides evidence for and against accepted therapies Coverage includes an introduction to cardiovascular disease methodology treatment trials prevention trials and much more Features over 230 helpful illustrations Proceedings of "Practical Issues in Data Monitoring of Clinical Trials" Susan Ellenberg, 1993

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