

2nd Edition

Data Monitoring Committees in Clinical Trials

A Practical Perspective

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THOMAS R. FLEMING
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STATISTICS IN PRACTICE

WILEY

Data Monitoring Committees In Clinical Trials A Practical Perspective

**Susan S. Ellenberg, Thomas R.
Fleming, David L. DeMets**



Data Monitoring Committees In Clinical Trials A Practical Perspective:

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

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Data and Safety Monitoring Committees in Clinical Trials Jay Herson, 2016-12-19

Praise for the first edition Given the author's years of experience as a statistician and as a founder of the first DMC in pharmaceutical industry trials I highly recommend this book not only for experts because of its cogent and organized presentation but more importantly for young investigators who are seeking information about the logistical and philosophical aspects of a DMC

S T Ounpraseuth The American Statistician In the first edition of this well regarded book the author provided a groundbreaking and definitive guide to best practices in pharmaceutical industry data monitoring committees DMCs Maintaining all the material from the first edition and adding substantial new material Data and Safety Monitoring Committees in Clinical Trials Second Edition is ideal for training professionals to serve on their first DMC as well as for experienced clinical and biostatistical DMC members sponsor and regulatory agency staff The second edition guides the reader through newly emerging DMC responsibilities brought about by regulations emphasizing risk vs benefit and the emergence of risk based monitoring It also provides the reader with many new statistical methods clinical trial designs and clinical terminology that have emerged since the first edition The references have been updated and the very popular end of chapter Q A section has been supplemented with many new experiences since the first edition New to the Second Edition Presents statistical methods tables listings and graphs appropriate for safety review efficacy analysis and risk vs benefit analysis SPERT and PRISMA initiatives Newly added interim analysis for efficacy and futility section DMC responsibilities in SUSARs Serious Unexpected Serious Adverse Reactions basket trials umbrella trials dynamic treatment strategies SMART trials pragmatic trials biosimilar trials companion diagnostics etc DMC responsibilities for data quality and fraud detection Fraud Recovery Plan Use of patient reported outcomes of safety Use of meta analysis and data outside the trial New ideas for training and compensation of DMC members Jay Herson is Senior Associate Biostatistics Johns Hopkins Bloomberg School of

Public Health where he teaches courses on clinical trials and drug development based on his many years experience in clinical trials in academia and the pharmaceutical industry

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 a minimum the statistician may still find the principles and fundamentals presented in this text useful

Principles and Practice of Clinical Research John I. Gallin, Frederick P Ognibene, 2012-05-31 This expanded third edition provides an introduction to the conduct of clinical research as well as more comprehensive and expansive content about the infrastructure necessary for a successful clinical research organization or enterprise With authors who are experts in clinical research in both the public and private sectors this publication provides essential information to clinical investigators who wish to develop and conduct well designed patient based research protocols that comply with rigorous study design ethical and regulatory requirements

Practical Considerations for Adaptive Trial Design and Implementation Weili He, José Pinheiro, Olga M. Kuznetsova, 2014-10-15 This edited volume is a definitive text on adaptive clinical trial designs from creation and customization to utilization As this book covers the full spectrum of topics involved in the adaptive designs arena it will serve as a valuable reference for researchers working in industry government and academia The target audience is anyone involved in the planning and execution of clinical trials in particular statisticians clinicians pharmacometricians clinical operation specialists drug supply managers and infrastructure providers In spite of

the increased efficiency of adaptive trials in saving costs and time ultimately getting drugs to patients sooner their adoption in clinical development is still relatively low One of the chief reasons is the higher complexity of adaptive design trials as compared to traditional trials Barriers to the use of clinical trials with adaptive features include the concerns about the integrity of study design and conduct the risk of regulatory non acceptance the need for an advanced infrastructure for complex randomization and clinical supply scenarios change management for process and behavior modifications extensive resource requirements for the planning and design of adaptive trials and the potential to relegate key decision makings to outside entities There have been limited publications that address these practical considerations and recommend best practices and solutions This book fills this publication gap providing guidance on practical considerations for adaptive trial design and implementation The book comprises three parts Part I focuses on practical considerations from a design perspective whereas Part II delineates practical considerations related to the implementation of adaptive trials Putting it all together Part III presents four illustrative case studies ranging from description and discussion of specific adaptive trial design considerations to the logistic and regulatory issues faced in trial implementation Bringing together the expertise of leading key opinion leaders from pharmaceutical industry academia and regulatory agencies this book provides a balanced and comprehensive coverage of practical considerations for adaptive trial design and implementation

Handbook of Statistics in Clinical Oncology John Crowley,Antje Hoering,Megan Othus,2025-12-31 Since the third edition of this handbook significant advances have transformed the field of oncology Most cancer types now offer multiple treatment options with immunotherapies and targeted therapies becoming the standard of care Master protocols which allow the addition of new treatment arms without requiring new protocols have gained popularity not only to expedite the approval process for new therapies but also to ensure that patients receive the most beneficial treatments tailored to their individual needs This revised edition features contributions from leading cancer trial statisticians providing expert insights into modern oncology trial design and methodology The handbook is structured into five key parts Part 1 Cancer prevention and screening trial designs including risk prediction models and prevention trials Part 2 Early phase trial designs covering dose finding studies selection designs and multi strata trials Part 3 Late stage trial designs including approaches for IO therapies cure rate models targeted agents and considerations for pediatric oncology trials Part 4 Trial conduct and operations addressing best practices for Data Monitoring Committees DMCs SWOG CRAB calculators pragmatic trials and clinical trial innovation Part 5 Beyond primary endpoints exploring surrogate endpoints microbiome research patient reported outcomes PROs and tree based partitioning methods This updated edition provides a comprehensive resource for researchers clinicians and statisticians involved in the evolving landscape of oncology clinical trials

Pharmacovigilance - E-BOOK Thao Doan,Fabio Lievano,Linda Scarazzini,Charles Schubert,Barbara Hendrickson,2024-11-20 Written by multidisciplinary experts in the fields of pharmaceutical and patient safety *Pharmacovigilance A Practical Approach* Second Edition provides a succinct easy

to digest overview of an increasingly critical area of medical safety From cover to cover this concise resource offers essential information for physicians and other health care professionals clinical researchers and regulators who need a comprehensive up to date source of information on the principles and practice of pharmacovigilance Presents vital easy to read cutting edge information on patient safety the pharmacology regulatory landscape and the current and future use of digital technologies Provides up to date coverage of hot topics in the field including pharmacodynamic and safety precision medicine immunogenicity vaccine hesitancy and safety genetic toxicology and adverse events Contains new chapters on pre clinical safety assessment pharmacogenetics first in human trials product aggregate safety assessment data monitoring committees and more Offers new and expanded coverage of pharmacovigilance in early pre clinical drug development through post marketing surveillance as well as a blueprint for training future pharmacovigilance professionals Includes real world case studies to ensure content is relevant and applicable to everyday practice Discusses a range of topics across disciplines and how they relate to pharmacovigilance including behavioral science patient perspectives and risk communication Any additional digital ancillary content may publish up to 6 weeks following the publication date **Cardiovascular**

Therapeutics Elliott M. Antman, 2007-01-22 This companion to Braunwald's Heart Disease equips you with all of today's most effective therapeutic guidelines and management solutions for the full range of heart disease patients It reflects the most recent standards for drug management as well as the latest in new technologies Reorganized to mirror your changing practice each cardiovascular problem based section offers a chapter on pharmacologic treatment with a minimum of pathophysiology a chapter on catheter based or minimally invasive interventions and a discussion of surgical options You'll also find a brand new chapter on gene therapy and stem cell therapy plus new chapters on many other rapidly developing areas of practice The result is an outstanding single volume source for state of the art clinically oriented guidance on both common and unusual areas of cardiovascular treatment Facilitates the decision making process clinicians face when choosing among various cardiovascular therapeutic options covers the latest concepts in pathophysiology evaluation and management of patients with cardiovascular disorders Addresses pharmacological interventional and surgical management approaches for each type of cardiovascular disease putting advice on the full range of therapeutic options at your disposal Keeps you current with brand new chapters on gene therapy and stem cell therapy unstable and chronic stable angina management of unstable angina and non ST elevation myocardial infarction devices for heart failure and arrhythmias prevention of ischemic disease the regulatory approval process for new cardiovascular drugs and devices and more Delivers a fully revised section on Heart Failure that explores cardiac resynchronization therapy surgical interventions ambulatory management hospital management and cardiac transplantation and circulatory support devices Offers a completely updated section on Other Cardiovascular Conditions that addresses issues such as pharmacologic treatment of cardiovascular disease during pregnancy care for adults with congenital heart disease treatment of primary pulmonary hypertension prevention and

treatment of infective endocarditis treatment of pericardial disease and rehabilitation of the patient with cardiovascular disease Reflects a new emphasis on the role of diet and exercise in the management of cardiovascular problems in conformity with ACC AHA ESC guidelines **Data and Safety Monitoring in Clinical Trials** Michelle Denise Roth-Cline,2006

AMSTAT News American Statistical Association,2009 *Clinical Trials in Heart Disease* JoAnn E. Manson,2004 This new edition covers important new trials in cardiology therapies and prevention of cardiovascular problems The world authorities on pharmacologic clinical trials write about the trials the outcomes and importance for clinical practice This book gives the general cardiologist insight into the development of new therapies in cardiology as well as the process of how trials were used for those therapies In addition to providing a manual for how to establish trials trials for treatment and prevention are covered Evidence based research to guide clinical practice Coverage of treatment trials including Glycoprotein IIb/IIIa receptor inhibitors aspirin drug therapies for arrhythmias and pacing Expanded section on prevention of cardiac disease Covers both prevention and treatment Data and Safety Monitoring Boards in Randomized Trials Coronary Artery Bypass Surgery Implantable Cardioverter Defibrillators and Cardiac Resynchronization Therapy Postmenopausal Hormone Therapy

Wiley Encyclopedia of Clinical Trials Lisa Marie Sullivan,Joseph Massaro,2008 Here you will find more than 500 entries from the world's leading experts in the field on the basic concepts methodologies and applications in clinical trials The range of topics includes basic statistical concepts design and analysis of clinical trials ethics regulatory issues and methodologies for clinical data management and analysis *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

Nondetects and Data Analysis Dennis R. Helsel,2005 *STATISTICS IN PRACTICE* Statistical methods for interpreting and analyzing censored environmental data *Nondetects And Data Analysis* Statistics for Censored Environmental Data provides solutions for environmental scientists and professionals who need to interpret and analyze data that fall below the laboratory detection limit Adapting survival analysis methods that have been successfully used in medical and industrial research the author demonstrates for the first time their practical applications for studies of trace chemicals in air water soils and biota Readers quickly become proficient in these methods through the use of real world examples that are solved using MINITAB Release 14 a popular statistical software package as well as other commonly used software packages Everything needed to

master these innovative statistical methods is provided including Accompanying Web site featuring answers to book exercises and datasets as well as MINITAB macros to perform methods which are not available in the commercial version Methods for data with multiple detection limits Solutions for research studies in which all data are below detection limits Techniques for constructing confidence prediction and tolerance intervals for data with nondetects Methods for data with multiple detection limits Chapters are organized by objective such as computing intervals comparing groups and correlations which enables readers to more easily apply the text to their particular research and goals Extensive references to the literature for more in depth research are provided however the text itself avoids complex math and calculus making it accessible to anyone in the environmental sciences Environmental scientists and professionals will find the hands on guidance and practical examples invaluable

Competing Risks Melania Pintilie, 2006-10-06 The book presents an introduction to the topic for statisticians who have not any exposure to competing risks and for non statisticians whose research involves time to event data The analysis of such data is usually referred to as survival analysis and also called as analysis of incomplete data and presents the software available to perform the analysis in R and includes macros for analysis in SAS

A Comparison of Adaptive Methods for the Analysis of Clinical Trials Alice Rogot Pressman, 2009

Statistical Methods for Dose-Finding Experiments Sylvie Chevret, 2006-05-26 Dose finding experiments define the safe dosage of a drug in development in terms of the quantity given to a patient Statistical methods play a crucial role in identifying optimal dosage Used appropriately these methods provide reliable results and reduce trial duration and costs In practice however dose finding is often done poorly with widely used conventional methods frequently being unreliable leading to inaccurate results However there have been many advances in recent years with new statistical techniques being developed and it is important that these new techniques are utilized correctly Statistical Methods for Dose Finding Experiments reviews the main statistical approaches for dose finding in phase I II clinical trials and presents practical guidance on their correct use Includes an introductory section summarizing the essential concepts in dose finding Contains a section on algorithm based approaches such as the traditional 3 3 design and a section on model based approaches such as the continual reassessment method Explains fundamental issues such as how to stop trials early and how to cope with delayed or ordinal outcomes Discusses in detail the main websites and software used to implement the methods Features numerous worked examples making use of real data Statistical Methods for Dose Finding Experiments is an important collaboration from the leading experts in the area Primarily aimed at statisticians and clinicians working in clinical trials and medical research there is also much to benefit graduate students of biostatistics

Selection Bias and Covariate Imbalances in Randomized Clinical Trials Vance Berger, 2005-05-27 Baseline data in clinical trials consists of information regarding patients that is measured at the outset prior to randomization or treatment with study medications In studies where important baseline factors appear well balanced it can be reasonably concluded that any differences in outcome

between the intervention and control groups are a real effect of treatment The common assumption that any baseline differences in a randomized study are necessarily random is however misplaced Selection bias can and does occur even in randomized clinical trials Steps need to be taken in order to ensure that this does not compromise the integrity of clinical trials hence Selection Bias and Covariate Imbalances in Randomized Clinical Trials offers the first comprehensive treatment of the subject and the methodology involved Provides an overview of the hierarchy of study designs and justifies the position of randomized trials at the top of this hierarchy Discusses the strengths and defects of randomization and provides real evidence to justify concern regarding its defects Outlays the damaging consequences that selection bias causes when it does occur Considers courses of action that can be taken to manage contain the problem Presents methods that can be used to detect selection bias in randomized trials and methods to correct for selection bias Concludes by providing a comprehensive plan for managing baseline imbalances and selection bias in randomized trials and proposing open problems for future research Selection Bias and Covariate Imbalances in Randomized Clinical Trials provides an in depth overview of a key aspect in the design and analysis of clinical trials featuring modern and novel approaches to the methodology described Illustrated with case studies this book introduces groundbreaking ideas and research that will be invaluable to researchers and practitioners who design and analyse clinical trials It will also be of interest to graduate students within the field of biostatistics

Journal of the American Statistical Association ,2009

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