

DATA MONITORING *in* **CLINICAL TRIALS**

A Case Studies Approach

*David L. DeMets
Curt D. Furberg
Lawrence M. Friedman
Editors*



Springer

Data Monitoring In Clinical Trials A Case Studies Approach

**Karl E. Peace, Ding-Geng
Chen, Sandeep Menon**



Data Monitoring In Clinical Trials A Case Studies Approach:

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 potential monitoring 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 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

Modern Approaches to Clinical Trials Using SAS Sandeep Menon, Richard C. Zink, 2015-12-09 Get the tools you need to use SAS in clinical trial design Unique and multifaceted Modern Approaches to Clinical Trials Using SAS Classical Adaptive and Bayesian Methods edited by Sandeep M Menon and Richard C Zink thoroughly covers several domains of modern clinical trial design classical group sequential adaptive and Bayesian methods that are applicable to and widely used in various phases of pharmaceutical development Written for biostatisticians pharmacometricians clinical developers and statistical programmers involved in the design analysis and interpretation of clinical trials as well as students in graduate and postgraduate programs in statistics or biostatistics the book touches on a wide variety of topics including dose response and dose escalation designs sequential methods to stop trials early for overwhelming efficacy safety or futility Bayesian designs that incorporate historical data adaptive sample size re estimation adaptive randomization to allocate subjects to more effective treatments and population enrichment designs Methods are illustrated using clinical trials from diverse therapeutic areas including dermatology endocrinology infectious disease neurology oncology and rheumatology Individual chapters are authored by renowned contributors experts and key opinion leaders from the pharmaceutical medical device industry or academia Numerous real world examples and sample SAS code enable users to readily apply novel clinical trial design and analysis methodologies in practice

The Oxford Textbook of Clinical Research Ethics Ezekiel J. Emanuel, 2008-05 The Oxford Textbook of Clinical Research Ethics is the first systematic and comprehensive reference on clinical research ethics Under the editorship of experts from the National Institutes of Health of the United States the book offers a wide ranging and systematic examination of all aspects of research with human beings Considering historical triumphs of research as well as tragedies the textbook provides a framework for analysing the ethical aspects of research studies with human beings Through both conceptual analysis and systematic reviews of empirical data the textbook examines

issues ranging from scientific validity fair subject selection risk benefit ratio independent review and informed consent as well as focused consideration of international research ethics conflicts of interests and other aspects of responsible conduct of research The editors of The Oxford Textbook of Clinical Research Ethics offer a work that critically assesses and advances scholarship in the field of human subjects research with human beings

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

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

Statistical Approaches in Oncology Clinical Development Satrajit Roychoudhury, Soumi Lahiri, 2018-12-07

Statistical Approaches in Oncology Clinical Development Current Paradigm and Methodological Advancement presents an overview of statistical considerations in oncology clinical trials both early and late phase of development It illustrates how novel statistical methods can enrich the design and analysis of modern oncology trials The authors include many relevant real life examples from the pharmaceutical industry and academia based on their first hand experience Along with relevant references the book highlights current regulatory views The book covers all aspects of cancer clinical trial starting from early phase development The early part of the book covers novel phase I dose escalation design exposure response analysis and innovative phase II design This includes early development strategy for cancer immunotherapy trials The contributors also emphasized the role of biomarker and modern era of precision medicine The second part focuses on the late stage development This includes the application of adaptive design safety analysis and quality of life QoL data analysis The final part discusses current regulatory perspective and challenges Features Covers a wide spectrum of topics related to real life statistical challenges in oncology clinical trials Provides a comprehensive overview of novel statistical methods to improve trial design and statistical analysis Detailed case studies illustrate the real life applications Satrajit Roychoudhury is a Senior Director and a member of the Statistical Research and Innovation group in Pfizer Inc Prior to joining he was a member of Statistical Methodology and consulting group in Novartis He has 11 years of extensive experience in working with different phases of clinical trial His area of research includes early phase oncology trials survival analysis model informed drug development and use of Bayesian methods in clinical trials He is industry co chair for the ASA Biopharmaceutical Section Regulatory Industry Workshop and has provided statistical training in major conferences including the Joint Statistical

Meetings ASA Biopharmaceutical Section Regulatory Industry Workshop and ICSA Applied Statistics Symposium Soumi Lahiri has 12 years of extensive experience in working different therapeutic areas She is the former Director of Biostatistics in Clinical Oncology GlaxoSmithKline She has also worked in the oncology division of Novartis Pharmaceutical Company for two years She is an active member of the ASA Biopharmaceutical section and former chair of the membership committee

Biopharmaceutical Applied Statistics Symposium Karl E. Peace, Ding-Geng Chen, Sandeep Menon, 2018-08-20 This BASS book Series publishes selected high quality papers reflecting recent advances in the design and biostatistical analysis of biopharmaceutical experiments particularly biopharmaceutical clinical trials The papers were selected from invited presentations at the Biopharmaceutical Applied Statistics Symposium BASS which was founded by the first Editor in 1994 and has since become the premier international conference in biopharmaceutical statistics The primary aims of the BASS are 1 to raise funding to support graduate students in biostatistics programs and 2 to provide an opportunity for professionals engaged in pharmaceutical drug research and development to share insights into solving the problems they encounter The BASS book series is initially divided into three volumes addressing 1 Design of Clinical Trials 2 Biostatistical Analysis of Clinical Trials and 3 Pharmaceutical Applications This book is the first of the 3 volumebook series The topics covered include A Statistical Approach to Clinical Trial Simulations Comparison of Statistical Analysis Methods Using Modeling and Simulation for Optimal Protocol Design Adaptive Trial Design in Clinical Research Best Practices and Recommendations for Trial Simulations in the Context of Designing Adaptive Clinical Trials Designing and Analyzing Recurrent Event Data Trials Bayesian Methodologies for Response Adaptive Allocation Addressing High Placebo Response in Neuroscience Clinical Trials Phase I Cancer Clinical Trial Design Single and Combination Agents Sample Size and Power for the Mixed Linear Model Crossover Designs in Clinical Trials Data Monitoring Structure for Clinical Trials and Sequential Monitoring Procedures Design and Data Analysis for Multiregional Clinical Trials Theory and Practice Adaptive Group Sequential Multi regional Outcome Studies in Vaccines Development and Validation of Patient reported Outcomes Interim Analysis of Survival Trials Group Sequential Analyses and Conditional Power A Non proportional Hazards Perspective **Introduction to Surgical Trials** Stephen Lyman, Olufemi R. Ayeni, Jason L. Koh, Norimasa Nakamura, Jón Karlsson, 2025-02-25 Filling a gap in literature this book examines surgical trials with a special focus on the underlying principles challenges and best practices to successfully conduct rigorous surgical research While randomized controlled trials RCTs remain the gold standard for evaluation of the safety and efficacy of most medical interventions they are particularly difficult to implement successfully in the context of surgery As a result recruitment rates are often extremely low crossover from non operative to operative is common and patients randomly allocated to surgery often simply decline to have the procedure All of these challenges call into question the recent generalizability and fundamental quality of traditional surgical RCTs As such this book explores advanced alternative trial design methods and describes the current regulatory environment around the world Designed as a

practical guide it is a valuable tool for surgeons epidemiologist and biostatisticians involved in this challenging field

Epidemiology and Medical Statistics ,2007-11-21 This volume representing a compilation of authoritative reviews on a multitude of uses of statistics in epidemiology and medical statistics written by internationally renowned experts is addressed to statisticians working in biomedical and epidemiological fields who use statistical and quantitative methods in their work While the use of statistics in these fields has a long and rich history explosive growth of science in general and clinical and epidemiological sciences in particular have gone through a sea of change spawning the development of new methods and innovative adaptations of standard methods Since the literature is highly scattered the Editors have undertaken this humble exercise to document a representative collection of topics of broad interest to diverse users The volume spans a cross section of standard topics oriented toward users in the current evolving field as well as special topics in much need which have more recent origins This volume was prepared especially keeping the applied statisticians in mind emphasizing applications oriented methods and techniques including references to appropriate software when relevant Contributors are internationally renowned experts in their respective areas Addresses emerging statistical challenges in epidemiological biomedical and pharmaceutical research Methods for assessing Biomarkers analysis of competing risks Clinical trials including sequential and group sequential crossover designs cluster randomized and adaptive designs Structural equations modelling and longitudinal data analysis

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