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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

this concise e book provides clinicians as well as administrative personnel involved in clinical research with an understanding of documentation related to clinical trial monitoring activities at each stage of the study from planning and set up through conduct and close out

the cra s guide to monitoring clinical research now in its third edition continues to be a key resource for both novice and experienced cras seeking to learn more about the field of monitoring or to better understand their roles and responsibilities as the industry becomes more global and technologically focused with helpful tips and strategies checklists personal experiences key takeaways and exercises plus new chapters on clinical trial roles and responsibilities monitoring for device and biologic trials globalization of studies edc and more the cra s guide is a must have training and educational tool that you ll refer to again and again topics include a comprehensive review of cra roles and responsibilities understanding regulations and gcps study initiation and monitoring plans recruiting and retaining study subjects the informed consent process conducting adverse event and safety monitoring preparing for audits and detecting fraud the future outlook job descriptions and current academic programs devices and biologics managing multi national trials irbs and data safety monitoring boards exercises with answers recommended for novice and experienced cras health professionals interested in pursuing a career as a study monitor instructors conducting training and educational programs

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

there has been substantial growth in the use of data monitoring committees in recent years by both government agencies and the pharmaceutical industry this growth has been brought about by increasing recognition of the value of such committees in safeguarding trial participants as well as protecting trial integrity and the validity of conclusions this very timely book describes the operation of data monitoring committees and provides an authoritative guide to their establishment purpose and responsibilities provides a practical overview of data monitoring in clinical trials describes the purpose responsibilities and operation of data monitoring committees provides directly applicable advice for those managing and conducting clinical trials and those serving on data monitoring committees gives insight into clinical data monitoring to those sitting on regulatory and ethical committees discusses issues pertinent to those working in clinical trials in both the us and europe the practical guidance provided by this book will be of use to professionals working in and or managing clinical trials in academic government and industry settings particularly medical statisticians clinicians trial co ordinators and those working in regulatory affairs and bioethics

this classic reference now updated with the newest applications and results addresses the fundamentals of such trials based on sound scientific methodology statistical principles and years of accumulated experience by the three authors

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

this book focuses on the practical application of good clinical practice gcp fundamentals and provides insight into roles and responsibilities included in planning executing and analyzing clinical trials the authors describe the design of quality into clinical trial planning and the application of regulatory scientific administrative business and ethical considerations describes the design of quality into the clinical trial planning has end of chapter questions and answers to check learning and comprehension includes charts that visually summarize the content and allow readers to cross reference details in relevant chapters offers a companion website containing supplemental training resources

the tutorials in biostatistics have become a very popular feature of the prestigious wiley journal statistics in medicine the introductory style and practical focus make them accessible to a wide audience including medical practitioners with limited statistical knowledge this book represents the first of two volumes presenting the best tutorials published in sim focusing on statistical methods in clinical studies topics include the design and analysis of clinical trials epidemiology survival analysis and data monitoring each tutorial is focused on a medical problem has been fully peer reviewed and edited and is authored by leading researchers in biostatistics many articles include an appendix on the latest developments since publication in the journal and additional references this will appeal to statisticians working in medical research as well as statistically minded clinicians biologists epidemiologists and geneticists it will also appeal to graduate students of biostatistics

the approach taken in this book is to studies monitored over time what the central limit theorem is to studies with only one analysis just as the central limit theorem shows that test statistics involving very different types of clinical trial outcomes are asymptotically normal this book shows that the joint distribution of the test statistics at different analysis times is asymptotically multivariate normal with the correlation structure of brownian motion the b value irrespective of the test statistic thus this book offers statisticians an accessible incremental approach to understanding brownian motion as related to clinical trials

the book is a result of 12 years of author s experience in 100 clinical trials to provide a focused insight of monitoring activities in more efficient and gcp compliant fashion the book covers all the essential activities and their applications which includes investigatory site selection and assessment development of monitoring plan site initiation review of essential clinical trial documents delegation of duties and responsibilities at individual trial site inventory planning crf review and collection coordination for data management sae review regulatory compliance investigational product management escalation and management of violations enrollments tracking payment correspondence site closure etc

this handbook is an excellent reflection of the growing maturity and methodological sophistication of the field of health technology assessment the handbook covers a spectrum of issues from primary evidence clinical trials through reviews and meta analysis to identifying and filling gaps in the evidence up to date clearly written and well edited the handbook is a needed addition to any personal or professional library dealing with health technology assessment professor david banta tno prevention and health the netherlands this text presents the most advanced knowledge on methodology in health care research and will form the backbone of many future studies paula roberts nurse researcher the effectiveness revolution both in research and clinical practice has tested available methods for health services research to the extreme how far can observational methods routine data and qualitative methods be used in health care evaluation what cost and outcome measures are appropriate and how should data be gathered with the support of over two million pounds from the british health technology assessment research programme the research project for this handbook has led to both a synthesis of all of the existing knowledge in these areas and an agenda for future debate and research the chapters and their authors have been selected through a careful process of peer review and provide a coherent and complete approach to the field the handbook has been a unique collaboration between internationally regarded clinicians statisticians epidemiologists social scientists health economists and ethicists it provides the most advanced thinking and the most authoritative resource for a state of the art review of methods of evaluating health care and will be required reading for anyone involved in health services research and management

today more than 75 percent of pharmaceutical drug trials in the united states are being conducted in the private sector once the sole province of academic researchers these important studies are now being outsourced to non academic physicians according to jill a fisher this major change in the way medical research is performed is the outcome of two problems in u s health care decreasing revenue for physicians and decreasing access to treatment for patients as physicians report diminishing income due to restrictive relationships with insurers increasing malpractice insurance premiums and inflated overhead costs to operate private practices they are attracted to pharmaceutical contract research for its lucrative return clinical trials also provide limited medical access to individuals who have no or inadequate health insurance because they offer free doctors visits diagnostic tests and

medications to participants focusing on the professional roles of those involved as well as key research practices fisher assesses the risks and advantages for physicians and patients alike when pharmaceutical drug studies are used as an alternative to standard medical care a volume in the critical issues in health and medicine series edited by rima d apple and janet golden

the development of new drugs is very complex costly and risky its success is highly dependent on an intense collaboration and interaction between many departments within the drug development organization external investigators and service providers in constant dialogue with regulatory authorities payers academic experts clinicians and patient organizations within the different phases of the drug life cycle drug development is by far the most crucial part for the initial and continued success of a drug on the market this book offers an introduction to the field of drug development with a clear overview of the different processes that lead to a successful new medicine and of the regulatory pathways that are used to launch a new drug that are both safe and efficacious this is the most comprehensive and detailed book on drug development i have ever read and i feel that it is likely to become a staple of drug development courses such as those taught at masters level in my own university i think in the light of increasing integration of company and academic approaches to drug development both sides can read this book and therefore this book could not be more timely professor mike coleman university of aston uk from his review of the final manuscript

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

statistical design monitoring and analysis of clinical trials second edition concentrates on the biostatistics component of clinical trials this new edition is updated throughout and includes five new chapters developed from the authors courses taught to public health and medical students residents and fellows during the past 20 years the text shows how biostatistics in clinical trials is an integration of many fundamental scientific principles and statistical methods the book begins with ethical and safety principles core trial design concepts the principles and methods of sample size and power calculation and analysis of covariance and

stratified analysis it then focuses on sequential designs and methods for two stage phase ii cancer trials to phase iii group sequential trials covering monitoring safety utility and efficacy the authors also discuss the development of sample size reestimation and adaptive group sequential procedures phase 2 3 seamless design and trials with predictive biomarkers exploit multiple testing procedures and explain the concept of estimand intercurrent events and different missing data processes and describe how to analyze incomplete data by proper multiple imputations this text reflects the academic research commercial development and public health aspects of clinical trials it gives students and practitioners a multidisciplinary understanding of the concepts and techniques involved in designing monitoring and analyzing various types of trials the book s balanced set of homework assignments and in class exercises are appropriate for students and researchers in bio statistics epidemiology medicine pharmacy and public health

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

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