

The CRA's Guide To Monitoring Clinical Research

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A Guide to Patient Recruitment and Retention
Hemodynamic Monitoring in the Critically Ill
Statistical Design, Monitoring, and Analysis of Clinical Trials
New York Court of Appeals. Records and Briefs. Karen E. Woodin
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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

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

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

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

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 primary goals of clinical research monitoring are to assure adequate protection of the rights of human subjects and the safety of all subjects involved in clinical investigations or clinical trials and the quality and integrity of the data generated from clinical trials adequate monitoring of clinical trials can prevent the occurrence of significant problems which may affect the entire process of bringing a new drug to market the proper monitoring of clinical trials is a challenge in spite of well established regulations and guidance there remain many monitoring related concerns in clinical trials e g protocol deviations and violations irb violations improper adverse event reporting etc the survey results indicate that clinical research coordinators believe that there are concerns in the monitoring process and that the quality of monitoring varies from monitor to monitor results also suggest that some monitors are exceptional where as some monitors are abysmal

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

patient recruitment and retention are clearly complex and challenging components of

the clinical trials process in the industry s foremost resource a guide to patient recruitment and retention the authors provide a wealth of practical advice and quantifiable examples on every aspect of patient recruitment this book builds on the success of the original a guide to patient recruitment by introducing many innovative multi faceted strategies designed to recruit and retain patients in clinical trials book jacket

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 futility 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

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