Practical Guide To Clinical Data Management Third Edition

An introductory guide to clinical research, written specifically for junior doctors by a team of highly experienced authors. This practical book covers all areas that a junior doctor will need to consider, including funding, study design, ethics, data analysis, disseminating findings, and furthering one's research career.

Analyzing Longitudinal Clinical Trial Data: A Practical Guide provide practical and easy to implement approaches for bringing the latest theory on analysis of longitudinal clinical trial data into routine practice.?This book, with its example-oriented approach that includes numerous SAS and R code fragments, is an essential resource for statisticians and graduate students specializing in medical research. The authors provide clear descriptions of the relevant statistical theory and illustrate practical considerations for modeling longitudinal data. Topics covered include choice of endpoint and statistical test; modeling means and the correlations between repeated measurements; accounting for covariates; modeling categorical data; model verification; methods for incomplete (missing) data that includes the latest developments in sensitivity analyses, along with approaches for and issues in choosing estimands; and means for preventing missing data. Each chapter stands alone in its coverage of a topic. The concluding chapters provide detailed advice on how to integrate these independent topics into an over-arching study development process and statistical analysis plan.

The management of clinical data, from its collection during a trial to its extraction for analysis, has become a critical element in the steps to prepare a regulatory submission and to obtain approval to market a treatment. Groundbreaking on its initial publication nearly fourteen years ago, and evolving with the field in each iteration since then, the third edition of Practical Guide to Clinical Data Management includes important updates to all chapters to reflect the current industry approach to using electronic data capture (EDC) for most studies. See what’s new in the Third Edition: A chapter on the clinical trial process that explains the high level flow of a clinical trial from creation of the protocol through the study lock and provides the context for the clinical data management activities that follow Reorganized content reflects an industry trend that divides training and standard operating procedures for clinical data management into the categories of study startup, study conduct, and study closeout Coverage of current industry and Food and Drug Administration (FDA) approaches and concerns The book provides a comprehensive overview of the tasks involved in clinical data management and the computer systems used to perform those tasks. It also details the context of regulations that guide how those systems are used and how those regulations are applied to their installation and maintenance. Keeping the coverage practical rather than academic, the author hones in on the most critical information that impacts clinical trial conduct, providing a full end-to-end overview or introduction for clinical data managers.

Critical Thinking in Clinical Research explains the fundamentals of clinical research in a case-based approach. The core concept is to combine a clear and concise transfer of information and knowledge with an engagement of the reader to develop a mastery of learning and critical thinking skills. The book addresses the main concepts of clinical research, basics of biostatistics, advanced topics in applied biostatistics, and practical aspects of clinical research, with emphasis on clinical relevance across all medical specialties.

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.

This comprehensive, unified text on the principles and practice of clinical trials presents a detailed account of how to conduct the trials. It describes the design, analysis, and interpretation of clinical trials in a non-technical manner and provides a general perspective on their historical development, current status, and future strategy. Features examples derived from the author's personal experience.

A Practical Guide for Informationists: Supporting Research and Clinical Practice guides new informationists to a successful career, giving them a pathway to this savvier, more technically advanced, domain-focused role in modern day information centers and libraries. The book's broad scope serves as an invaluable toolkit for healthcare professionals, researchers and graduate students in information management, library and information science, data management, informatics, etc. Furthermore, it is also ideal as a textbook for courses in medical reference services/medical informatics in MLIS programs. Offer examples (e.g. case studies) of ways of delivering information services to end users Includes recommendations, evidence and worksheets/take-aways/templates to be repurposed and adapted by the reader Aimed at the broad area of healthcare and research libraries

Clinical data management (CDM) has changed from being an essentially clerical task in the late 1970s and early 1980s to a highly computerized, highly specialized field today. And clinical data manages have had to adapt their data management systems and processes accordingly. Practical Guide to Clinical Data Management steers you through a basic understanding of the role of data management in clinical trials and includes more advanced topics such as CDM systems, SOPs, and quality assurance. This book helps you ensure GCP, manage laboratory data, and deal with the kinds of clinical data that can cause difficulties in database applications. With the tools this book provides, you'll learn how to: Ensure that your DMB system is in compliance with federal regulations Build a strategic data management and databsing plan Track and record CRFs Deal with problem data, adverse event data, and legacy data Manage and store lab data Identify and manage discrepancies Ensure quality control over reports Choose a CDM system that is right for your company Create and implement a system validation plan and process Set up and enforce data collection standards Develop test plans and change control systems This book is your guide to finding the most successful and practical options for effective clinical data management.

"The publication of the second edition of this manual comes at an important juncture in the history of clinical research. As advances in information technology make it possible to link individuals and groups in diverse locations in jointly seeking the answers to pressing global health problems, it is critically important to remain vigilant about moral and ethical safeguards for every patient enrolled in a trial. Those who study this manual will be well aware of how to ensure patient safety along with fiscal responsibility, trial efficiency, and research integrity." —Robert Harrington, Professor of Medicine, Director, Duke Clinical Research Institute, Durham, North Carolina, USA The Duke Clinical Research Institute (DCRI) is one of the world's leading academic clinical research organizations; its mission is to develop and share knowledge that improves the care of patients around the world through innovative clinical research. This concise handbook provides a practical "nuts and bolts" approach to the process of conducting clinical trials, identifying methods and techniques that can be replicated at other institutions and medical practices. Designed for investigators, research coordinators, CRO personnel, students, and others who have a desire to learn about clinical trials, this manual begins with an overview of the historical framework of clinical research, and leads the reader through a discussion of safety concerns and resulting regulations. Topics include Good Clinical Practice, informed consent, management of subject safety and data, as well as monitoring and reporting adverse events. Updated to reflect recent regulatory and clinical developments, the manual reviews the conduct of clinical trials research in an increasingly global context. This new edition has been further

expanded to include: In-depth information on conducting clinical trials of medical devices and biologics The role and responsibilities of Institutional Review Boards, and Recent developments regarding subject privacy concerns and regulations. Ethical documents such as the Belmont Report and the Declaration of Helsinki are reviewed in relation to all aspects of clinical research, with a discussion of how researchers should apply the principles outlined in these important documents. This graphically appealing and eminently readable manual also provides sample forms and worksheets to facilitate data management and regulatory record retention; these can be modified and adapted for use at investigative sites.

This book aims to demystify clinical trials. It is divided into five sections: fundamentals of trial design, alternative trial designs, basics of statistical analysis, special trial issues in data analysis, and reporting of trials. Using simple language the book explains with illustrations of numerous trial examples, the conceptual and methodological issues that occur at all stages of clinical trial covering trial design, conduct, analysis and reporting. The book is an educational and approachable reference in a difficult area of medicine where clinicians often feel uncertain and this material helps them review, appraise and publish trials and clinical evidence.

The second edition of this innovative work again provides a unique perspective on the clinical discovery process by providing input from experts within the NIH on the principles and practice of clinical research. Molecular medicine, genomics, and proteomics have opened vast opportunities for translation of basic science observations to the bedside through clinical research. As an introductory reference it gives clinical investigators in all fields an awareness of the tools required to ensure research protocols are well designed and comply with the rigorous regulatory requirements necessary to maximize the safety of research subjects. Complete with sections on the history of clinical research and ethics, copious figures and charts, and sample documents it serves as an excellent companion text for any course on clinical research and as a must-have reference for seasoned researchers. *Incorporates new chapters on Managing Conflicts of Interest in Human Subjects Research, Clinical Research from the Patient's Perspective, The Clinical Researcher and the Media, Data Management in Clinical Research, Evaluation of a Protocol Budget, Clinical Research from the Industry Perspective, and Genetics in Clinical Research *Addresses the vast opportunities for translation of basic science observations to the bedside through clinical research *Delves into data management and addresses how to collect data and use it for discovery *Contains valuable, up-to-date information on how to obtain funding from the federal government

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.

Clinical Data-Mining (CDM) involves the conceptualization, extraction, analysis, and interpretation of available clinical data for practice knowledge-building, clinical decision-making and practitioner reflection. Depending upon the type of data mined, CDM can be qualitative or quantitative; it is generally retrospective, but may be meaningfully combined with original data collection.Any research method that relies on the contents of case records or information systems data inevitably has limitations, but with proper safeguards these can be minimized. Among CDM's strengths however, are that it is unobtrusive, inexpensive, presents little risk to research subjects, and is ethically compatible with practitioner value commitments. When conducted by practitioners, CDM yields conceptual as well as data-driven insight into their own practice- and program-generated questions.This pocket guide, from a seasoned practice-based researcher, covers all the basics of conducting practitioner-initiated CDM studies or CDM doctoral dissertations, drawing extensively on published CDM studies and completed CDM dissertations from multiple social work settings in the United States, Australia, Israel, Hong Kong and the United Kingdom. In addition, it describes consulting principles for researchers interested in forging collaborative university-agency CDM partnerships, making it a practical tool for novice practitioner-researchers and veteran academic-researchers alike.As such, this book is an exceptional guide both for professionals conducting practice-based research as well as for social work faculty seeking an evidence-informed approach to practice-research integration.

Condensing the most important topics in all of clinical research in an easy to understand presentation. The 20 percent of what you need to know in order to be 80 percent proficient!The authors who have operated various levels of businesses in the clinical research industry since 2005 believe that more practical information pertaining to clinical research needs to be accessible to individuals who are new to the industry or are curious about entering the rewarding world of clinical trials.This book reads in an easy to understand style and is based on proven methods the authors have developed to train their own employees and students of their various clinical research academies throughout the years. Picking this up and absorbing the information will allow anyone to gain much better insight into the complicated dynamics of clinical research. This practical roadmap is all you will need to get started on your clinical trial journey!In this book you will learn about:Regulations and the history as well as evolution of GCP.Clinical Research Site OperationsMonitoring Dynamics and Typical Monitoring VistsCRO ActivitiesSponsor Level DynamicsIndustry VendorsCommon Career Opportunities and Employment Roadmaps

This brand-new book offers a reference guide to understanding and applying the rules for properly conducting clinical trials to meet the international quality standard – Good Clinical Practice – provided by the International Conference on Harmonization (ICH). The

work offers an updated perspective on the clinical research landscape within the context of the clinical trial regulatory frameworks in Europe and the USA. In addition to providing a historical review and a detailed definition of GPC regulations, it includes step-by-step explanations of all the requirements that researchers should bear in mind when designing and performing new trials. Further topics covered include: ethics of clinical research; the drug development process and evolution of regulations; investigator and sponsor responsibilities; and clinical trial protocols. Written by clinicians for clinicians, the book represents a valuable read also for researchers, pharmacists and all professionals involved in applications to the ethic committees, whose approval is required for new clinical studies.

Analysis of Clinical Trials Using SAS®: A Practical Guide, Second Edition bridges the gap between modern statistical methodology and real-world clinical trial applications. Tutorial material and step-by-step instructions illustrated with examples from actual trials serve to define relevant statistical approaches, describe their clinical trial applications, and implement the approaches rapidly and efficiently using the power of SAS. Topics reflect the International Conference on Harmonization (ICH) guidelines for the pharmaceutical industry and address important statistical problems encountered in clinical trials. Commonly used methods are covered, including dose-escalation and dose-finding methods that are applied in Phase I and Phase II clinical trials, as well as important trial designs and analysis strategies that are employed in Phase II and Phase III clinical trials, such as multiplicity adjustment, data monitoring, and methods for handling incomplete data. This book also features recommendations from clinical trial experts and a discussion of relevant regulatory guidelines. This new edition includes more examples and case studies, new approaches for addressing statistical problems, and the following new technological updates: SAS procedures used in group sequential trials (PROC SEQDESIGN and PROC SEQTEST) SAS procedures used in repeated measures analysis (PROC GLIMMIX and PROC GEE) macros for implementing a broad range of randomization-based methods in clinical trials, performing complex multiplicity adjustments, and investigating the design and analysis of early phase trials (Phase I dose-escalation trials and Phase II dose-finding trials) Clinical statisticians, research scientists, and graduate students in biostatistics will greatly benefit from the decades of clinical research experience and the ready-to-use SAS macros compiled in this book.

This book provides a practical guide to analysis of simple and complex method comparison data, using Stata, SAS and R. It takes the classical Limits of Agreement as a starting point, and presents it in a proper statistical framework. The model serves as a reference for reporting sources of variation and for providing conversion equations and plots between methods for practical use, including prediction uncertainty. Presents a modeling framework for analysis of data and reporting of results from comparing measurements from different clinical centers and/or different methods. Provides the practical tools for analyzing method comparison studies along with guidance on what to report and how to plan comparison studies and advice on appropriate software. Illustrated throughout with computer examples in R. Supported by a supplementary website hosting an R-package that performs the major part of the analyses needed in the area. Examples in SAS and Stata for the most common situations are also provided. Written by an acknowledged expert on the subject, with a long standing experience as a biostatistician in a clinical environment and a track record of delivering training on the subject. Biostatisticians, clinicians, medical researchers and practitioners involved in research and analysis of measurement methods and laboratory investigations will benefit from this book. Students of statistics, biostatistics, and the chemical sciences will also find this book useful.

This book is a practical, concise and clear guide to the process of risk stratification.

Practical Guide to Clinical Data ManagementCRC Press

The management of clinical data, from its collection during a trial to its extraction for analysis, has become a critical element in the steps to prepare a regulatory submission and to obtain approval to market a treatment. Groundbreaking on its initial publication nearly fourteen years ago, and evolving with the field in each iteration since then,

Clinical Surgery: A Practical Guide is a handbook for all trainees in surgery, providing an invaluable and expert guide to all aspects of clinical surgery that the trainee will encounter during their day to day work. General chapters on clinical examination, pre-operative, peri-operative and post-operative care are accompanied by expert guidance on how to deal with specific surgical problems, such as respiratory failure, wound healing, MRSA infection, tropical surgery and acute ischaemia. Further chapters provide invaluable information on topics including nutrition, anaesthsia, sutures and surgical incisions. The special problems associated with the surgical management of elderly patients are discussed, and the reader is introduced to the principles of surgical oncology and laparoscopic surgery. With its concise and easy-to read layout, Clinical Surgery: A Practical Guide is written by a team of expert surgeons, some of whom are also examiners for the Royal College of Surgeons. It is an invaluable on-the-job guide for Foundation level doctors on surgical rotation, as well as for those studying for the MRCS, FRCS and equivalent examinations.

This book teaches researchers how to resolve the ethical dilemmas that can arise at any stage in clinical research. In addition to explaining pertinent regulations and laws, Dr. Lo helps investigators understand the gaps and uncertainties in regulations, as well as situations in which merely complying with the law may not fulfill ethical responsibilities. Most chapters include real-life examples that the author walks through, discussing the salient issues and how to approach them. This book can be used in courses on research ethics that are required or encouraged by major National Institutes of Health grants in academic health centers.

Prediction models are important in various fields, including medicine, physics, meteorology, and finance. Prediction models will become more relevant in the medical field with the increase in knowledge on potential predictors of outcome, e.g. from genetics. Also, the number of applications will increase, e.g. with targeted early detection of disease, and individualized approaches to diagnostic testing and treatment. The current era of evidence-based medicine asks for an individualized approach to medical decision-making. Evidence-based medicine has a central place for meta-analysis to summarize results from randomized controlled trials; similarly prediction models may summarize the effects of predictors to provide individu- ized predictions of a diagnostic or prognostic outcome. Why Read This Book? My motivation for working on this book stems primarily from the fact that the development and applications of prediction models are often suboptimal in medical publications. With this book I hope to contribute to better understanding of relevant issues and give practical advice on better modelling strategies than are nowadays widely used. Issues include: (a) Better predictive modelling is sometimes easily possible; e.g. a large data set with high quality data is available, but all continuous predictors are dich- omized, which is known to have several disadvantages.

Design more effective social work programs with research data from your clinical files! A well-planned research program helps social workers provide consistent, effective services to their clients, but stretched budgets and tight schedules make it difficult to find the resources for data gathering. Clinical Data-Mining in Practice-Based Research shows how you can use the existing records already kept by every health-care institution as your primary data source. By analyzing documented clinical information, you can do groundbreaking research and custom-tailor programs to fit the specific needs of your department. Clinical Data-Mining in Practice-Based Research draws from the experiences of members of the Mount Sinai Department of Social Work staff. By analyzing case data, these professionals were able to identify biopsychosocial factors that affected social-health outcomes. These practice-based research strategies helped social work professionals see their own work more clearly and helped improve the quality of direct services, interventions, new programs, and case evaluations. Clinical Data-Mining in Practice-Based Research shows the benefits of practice-based research, including: enhancing clinical and administrative

functions encouraging direct-service workers to become more reflective fostering cooperation between social workers and other staff members designing earlier, easier, and more effective interventions contributing to continuing education for staff members improving patient care and satisfaction The detailed discussions in this book will help you apply these techniques toward improving your own service. Clinical Data-Mining in Practice-Based Research offers fresh and exciting ideas that can be applied in small health-care agencies or giant medical centers. It will become a trusted reference for administrators, social workers, researchers, and educators in the field.

This book provides practical guidance for statisticians, clinicians, and researchers involved in clinical trials in the biopharmaceutical industry, medical and public health organisations. Academics and students needing an introduction to handling missing data will also find this book invaluable. The authors describe how missing data can affect the outcome and credibility of a clinical trial, show by examples how a clinical team can work to prevent missing data, and present the reader with approaches to address missing data effectively. The book is illustrated throughout with realistic case studies and worked examples, and presents clear and concise guidelines to enable good planning for missing data. The authors show how to handle missing data in a way that is transparent and easy to understand for clinicians, regulators and patients. New developments are presented to improve the choice and implementation of primary and sensitivity analyses for missing data. Many SAS code examples are included – the reader is given a toolbox for implementing analyses under a variety of assumptions.

Recent decades have brought advances in statistical theory for missing data, which, combined with advances in computing ability, have allowed implementation of a wide array of analyses. In fact, so many methods are available that it can be difficult to ascertain when to use which method. This book focuses on the prevention and treatment of missing data in longitudinal clinical trials. Based on his extensive experience with missing data, the author offers advice on choosing analysis methods and on ways to prevent missing data through appropriate trial design and conduct. He offers a practical guide to key principles and explains analytic methods for the non-statistician using limited statistical notation and jargon. The book's goal is to present a comprehensive strategy for preventing and treating missing data, and to make available the programs used to conduct the analyses of the example dataset.

This easy-to-read reference book provides a practical approach for dealing with the legal and regulatory compliance issues involved in human research. Covering a broad range of topics, such as consent, confidentiality, subject recruitment and selection, the role of the investigator and Institutional Review Board, it offers timely and useful strategies for achieving regulatory compliance while reducing liability. In addition, insurance, quality management, accreditation, and risk management are topics examined in the book. The practical insights found in this volume are not found in other books on the subject. Clinical Trials and Human Research is a practical tool to help anyone involved in clinical research.

A clinical trial is complex, with numerous regulations, administrative processes, medical procedures, deadlines, and specific protocol instructions to follow. The Sourcebook for Clinical Trials provides a comprehensive overview of the clinical trial process covering the basics to more advances topics. The book discusses foundational elements defining clinical trials and types of research studies, research personnel and responsibilities, and understanding the role of HIPAA and PHI. The book also covers pre-trial preparation and regulatory requirements, subject recruitment, mechanics and trial conduct, review boards and agencies involved in the clinical trial process as well as post-trial study closeout. The inclusion of helpful resources, sample forms, and checklists make The Sourcebook for Clinical Trials an essential step-by-step resource for those involved in conducting, managing, or overseeing clinical trials. Offers guidance that is crucial for guaranteeing compliance to clinical trial protocols during each stage of the clinical trial process Lays out vital information in an easy, accessible format to keep investigative teams current on federal regulations and good clinical practice Provides up-to-date and extensive coverage of Federal and IRB regulations and helpful worksheets, templates, checklists, and protocol resources for clinical trial personnel to utilize

"The Fundamentals of Clinical Data Management" is a manual for Sponsors, CROs, Investigators, Clinical Trial Monitors and Managers and Clinical Research Professionals to learn the basic concepts of Clinical Data Management. This book will focus on the topic which includes: Clinical Information Flow, Roles and Responsibilities of CDM Personnel, Guidelines Associated with CDM, Data Management Plan, CRF Designing, Data Collection, Cleaning and Data Validation, Study setup and Database Designing, Laboratory Data and Adverse Event Data Management, Report Creation and Data Closure, Data Archiving, Privacy and Security etc.

Designing Clinical Research sets the standard for providing a practical guide to planning, tabulating, formulating, and implementing clinical research, with an easy-to-read, uncomplicated presentation. This edition incorporates current research methodology—including molecular and genetic clinical research—and offers an updated syllabus for conducting a clinical research workshop. Emphasis is on common sense as the main ingredient of good science. The book explains how to choose well-focused research questions and details the steps through all the elements of study design, data collection, quality assurance, and basic grant-writing. All chapters have been thoroughly revised, updated, and made more user-friendly.

A Comprehensive and Practical Guide to Clinical Trials provides an overview of the entire process of clinical research in one thorough and easy-to-read handbook that offers those involved in clinical research a clear understanding of how the components of a study are related. It focuses on the practical aspects of the preparation and execution of a clinical trial and offers tools and resources to help the entire team understand how their responsibilities tie together with the tasks and duties of other members. This allows for better planning and prioritization, and can lead to more effective and successful clinical trials. With practical examples, checklists and forms, this book is a useful guide for planning and conducting clinical trials from beginning to end. Describes the entire clinical trial management process from start to finish in a step-by-step guide Provides best practice elements, including case studies, practical examples, activities, and checklists Accompanied by a website with PowerPoint slides and an image bank

This practical guide covers the background to the development of clinical governance, suggests structures for implementation and addresses the main areas of clinical governance. Each chapter is summarized with key issues and implementation points.

This open access book comprehensively covers the fundamentals of clinical data science, focusing on data collection, modelling and clinical applications. Topics covered in the first section on data collection include: data sources, data at scale (big data), data stewardship (FAIR data) and related privacy concerns. Aspects of predictive modelling using techniques such as classification, regression or clustering, and prediction model validation will be covered in the second section. The third section covers aspects of (mobile) clinical decision support systems, operational excellence and value-based healthcare. Fundamentals of Clinical Data Science is an essential resource for healthcare professionals and IT consultants intending to develop and refine their skills in personalized medicine, using solutions based on large datasets

from electronic health records or telemonitoring programmes. The book's promise is "no math, no code"and will explain the topics in a style that is optimized for a healthcare audience.
How to perform and interpret multivariable analysis, using plain language rather than complex derivations.
Written in response to numerous requests by nurse practitioners and other graduate faculty for a nursing literature resource, this new two-color book is based on the Users' Guides to the Medical Literature: A Manual for Evidence-Based Practice by Dr. Gordon Guyatt and Dr. Drummond Rennie, published in 2001 by the AMA. Revised for the nursing audience, Evidence-Based Nursing is a reader-friendly, accessible guide that features plentiful examples from the nursing literature and the addition of specific nursing issues such as qualitative research, with direct application for clinical practice. Drs. DiCenso, Ciliska, and Guyatt are three of the leaders in the evidence-based nursing community and command worldwide recognition. Evidence-Based Nursing will enable nurses to frame their clinical questions in a way that will help them find and distinguish between strong and weak evidence; clearly understand study results; weigh the risks and benefits of management options; and apply the evidence to their individual patients to improve outcomes. This is the only book of its kind that helps nurses use the nursing literature effectively to solve patient problems. Three-step approach to dissecting a problem — to help find the best evidence and improve patient care, most questions can be divided into three parts: (1) Are the results valid? (2) What are the results? and (3) How can I apply the results to patient care? Part One - The Basics: Using the Nursing Literature provides a basic approach to the problems faced by nurses when determining optimal care, predicting patient progress, and protecting patients from potentially harmful side effects and includes a literature assessment summary and management recommendations. Part Two - Beyond the Basics: Using and Teaching the Principles of Evidence-Based Nursing expands on Part One, providing concrete examples through the presentation of cases. Two-part organization helps both beginners and those more accomplished at using the nursing literature. Clinical Scenario provides a brief but detailed description of a clinical situation that requires the application of research through a critical thinking process. Using the Guide examines a clinical scenario, and then evaluates the way in which research findings are collected, analyzed, and applied to the resolution of the problem presented in the scenario. Free CD-ROM contains everything found in the book, allowing for electronic outlining, content filtering, full-text searching, and alternative content organizations.
Phase I trials are a critical first step in the study of novel cancer therapeutic approaches. Their primary goals are to identify the recommended dose, schedule and pharmacologic behavior of new agents or new combinations of agents and to describe the adverse effects of treatment. In cancer therapeutics, such studies have particular challenges. Due to the nature of the effects of treatment, most such studies are conducted in patients with advanced malignancy, rather than in healthy volunteers. Further, the endpoints of these trials are usually measures adverse effects rather than molecular target or anti-tumor effects. These factors render the design, conduct, analysis and ethical aspects of phase I cancer trials unique. As the only comprehensive book on this topic, Phase I Cancer Clinical Trials is a useful resource for oncology trainees or specialists interested in understanding cancer drug development. New to this edition are chapters on Phase 0 Trials and Immunotherapeutics, and updated information on the process, pitfalls, and logistics of Phase I Trials
Regulatory bodies such as the European Medicine Agency have done tremendous work in collaboration with experts from the field to develop Good Clinical Practices that apply not only in Europe but also in emerging countries. Designed to be a teaching aid and reference guide, A Practical Guide to Human Research and Clinical focuses on ethics, regulations, and guidelines. Conducting a successful clinical trial requires not only a strong basic knowledge, but also hands-on practical training. The book explains the intricate details of the subject to readers by citing concrete cases, exercises, and templates along with the theoretical aspects. Prof. M.U.R Naidu and his co-authors address all aspects of clinical trials from clinical research, drug development, and quality to methodology, biostatistics, and pharmacovigilance.
Medical Data Management is a systematic introduction to the basic methodology of professional clinical data management. It emphasizes generic methods of medical documentation applicable to such diverse tasks as the electronic patient record, maintaining a clinical trials database, and building a tumor registry. This book is for all students in medical informatics and health information management, and it is ideal for both the undergraduate and the graduate levels. The book also guides professionals in the design and use of clinical information systems in various health care settings. It is an invaluable resource for all health care professionals involved in designing, assessing, adapting, or using clinical data management systems in hospitals, outpatient clinics, study centers, health plans, etc. The book combines a consistent theoretical foundation of medical documentation methods outlining their practical applicability in real clinical data management systems. Two new chapters detail hospital information systems and clinical trials. There is a focus on the international classification of diseases (ICD-9 and -10) systems, as well as a discussion on the difference between the two codes. All chapters feature exercises, bullet points, and a summary to provide the reader with essential points to remember. New to the Third Edition is a comprehensive section comprised of a combined Thesaurus and Glossary which aims to clarify the unclear and sometimes inconsistent terminology surrounding the topic.
Single-Case Methods in Clinical Psychology: A Practical Guide provides a concise and easily-accessible introduction to single-case research. This is a timely response to the increasing awareness of the need to look beyond randomised controlled trials for evidence to support best practice in applied psychology. The book covers the issues of design, the reliability and validity of measurement, and provides guidance on how to analyse single-case data using both visual and statistical methods. Single-case designs can be used to investigate an individual's response to psychological intervention, as well as to contribute to larger scale research projects. This book illuminates the common principles behind these uses. It describes how standardised measures can be used to evaluate change in an individual and how to develop idiographic measures that are tailored to the needs of an individual. The issue of replication and generalising beyond an individual are examined, and the book also includes a section on the meta-analysis of single-case data. The critical evaluation of single-case research is examined, from both the perspective of developing quality standards to evaluate research and maintaining a critical distance in reviewing one's own work. Single Case Methods in Clinical Psychology will provide invaluable guidance to postgraduate psychologists training to enter the professions of clinical, health and counselling psychology and is likely to become a core text on many courses. It will also appeal to clinicians seeking to answer questions about the effectiveness of therapy in individual cases and who wish to use the method to further the evidence-base for specific psychological interventions.