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6KPMHV - BROOKLYN MICAELA

Best practices for conducting effective and safe clinical trials Clinical trials are arguably the most important steps in proving drug effectiveness and safety for public use. They require intensive planning and organization and involve a wide range of disciplines: data management, biostatistics, pharmacology, toxicology, modeling and simulation, regulatory monitoring, ethics, and particular issues for given disease areas. Clinical Trials Handbook provides a comprehensive and thorough reference on the basics and practices of clinical trials. With contributions from a range of international authors, the book takes the reader through each trial phase, technique, and issue. Chapters cover every key aspect of preparing and conducting clinical trials, including: Interdisciplinary topics that have to be coordinated for a successful clinical trialData management (and adverse event reporting systems) Biostatistics, pharmacology, and toxicology Modeling and simulation Regulatory monitoring and ethics Particular issues for given disease areas-cardiology, oncology, cognitive, dementia, dermatology, neuroscience, and more With unique information on such current issues as adverse event reporting (AER) systems, adaptive trial designs, and crossover trial designs, Clinical Trials Handbook will be a ready reference for pharmaceutical scientists, statisticians, researchers, and the many other professionals involved in drug development.

An ideal health care system relies on efficiently generating timely, accurate evidence to deliver on its promise of diminishing the divide between clinical practice and research. There are growing indications, however, that the current health care system and the clinical research that guides medical decisions in the United States falls far short of this vision. The process of generating med-

ical evidence through clinical trials in the United States is expensive and lengthy, includes a number of regulatory hurdles, and is based on a limited infrastructure. The link between clinical research and medical progress is also frequently misunderstood or unsupported by both patients and providers. The focus of clinical research changes as diseases emerge and new treatments create cures for old conditions. As diseases evolve, the ultimate goal remains to speed new and improved medical treatments to patients throughout the world. To keep pace with rapidly changing health care demands, clinical research resources need to be organized and on hand to address the numerous health care questions that continually emerge. Improving the overall capacity of the clinical research enterprise will depend on ensuring that there is an adequate infrastructure in place to support the investigators who conduct research, the patients with real diseases who volunteer to participate in experimental research, and the institutions that organize and carry out the trials. To address these issues and better understand the current state of clinical research in the United States, the Institute of Medicine's (IOM) Forum on Drug Discovery, Development, and Translation held a 2-day workshop entitled Transforming Clinical Research in the United States. The workshop, summarized in this volume, laid the foundation for a broader initiative of the Forum addressing different aspects of clinical research. Future Forum plans include further examining regulatory, administrative, and structural barriers to the effective conduct of clinical research; developing a vision for a stable, continuously funded clinical research infrastructure in the United States; and considering strategies and collaborative activities to facilitate more robust public engagement in the clinical research enterprise.

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.

The editors (of U. Hospitals of Cleveland and Rx Trials, Inc.) offer a guide to the practical and ethical issues in the conduct of clinical research coordinators that places the topic in broad international perspective by including approaches from the European Union, Japan, Canada, and the United States. Thirteen chapters discuss ethics and human subjects protection, responsible conduct, the informed consent process, pediatric informed consent and assent, study implementation and start-up, recruitment and retention of research subjects, documentation, quality assurance in clinical trials, communication, education and training, and future trends in professionalization. Distributed in the US by BookMasters. Annotation :2006 Book News, Inc., Portland, OR

(booknews.com).

Law/Ethics

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.

Handbook for Clinical Trials of Imaging and Image-Guided Interventions is the first single-source, multi-disciplinary reference, based on the didactic sessions presented at the annual 'Clinical Trials Methodology Workshop' for radiologists, radiation oncologists and imaging scientists (sponsored by the Radiological Society of North America (RSNA)). It focuses on educating radiologists, radiation oncologists and those involved in imaging research with how to design and conduct clinical trials to evaluate imaging technology and imaging biomarkers. The internationally renowned contributors take a broad approach, starting with principles of technology assessment, and then move into specific topics covering the clinical trials of therapy and clinical research in imaging guided interventions including radiotherapy. They discuss the use of imaging as a predictor of therapeutic response, screening trial design, and the practicalities of how to run an efficient clinical trial and good working practices. Later chapters provide a comprehensive array of quantitative methods including: an introduction to statistical considerations in study design, biostatistical analysis methods and their role in clinical imaging research, methods for quantitative imaging biomarker studies, and an introduction to cost effectiveness analysis. Handbook for Clinical Trials of Imaging and Image-Guided Interventions will educate and prepare radiologists at all levels and in all capacities in planning and conducting clinical imaging trials.

This revised edition of a bestseller provides a logical, step-by-step guide to testing new drugs and treatment modalities in compliance with the latest FDA regulations. With current forms, ICH GCP information, FDA regulations, and other references, it shows readers how to manage a clinical research study effectively and efficiently.

Now published in its Second Edition, the Textbook of Clinical Trials offers detailed coverage of trial methodology in diverse areas of medicine in a single comprehensive volume. Praise for the First Edition: "... very useful as an introduction to clinical research, or for those planning specific studies within therapeutic or disease areas." BRITISH JOURNAL OF SURGERY, Vol. 92, No. 2, February 2005 The book's main concept is to describe the impact of clinical trials on the practice of medicine. It separates the information by therapeutic area because the impact of clinical trials, the problems encountered, and the numbers of trials in existence vary tremendously from specialty to specialty. The sections provide a background to the disease area and general clinical trial methodology before concentrating on particular problems experienced in that area. Specific examples are used throughout to address these issues. The Textbook of Clinical Trials, Second Edition: Highlights the various ways clinical trials have influenced the practice of medicine in many therapeutic areas Describes the challenges posed by those conducting clinical trials over a range of medical specialities and allied fields Additional therapeutic areas are included in this Second Edition to fill gaps in the First Edi-

tion as the number and complexity of trials increases in this rapidly developing area Newly covered or updated in the Second Edition: general surgery, plastic surgery, aesthetic surgery, palliative care, primary care, anaesthesia and pain, transfusion, wound healing, maternal and perinatal health, early termination, organ transplants, ophthalmology, epilepsy, infectious disease, neuro-oncology, adrenal, thyroid and urological cancers, as well as a chapter on the Cochrane network An invaluable resource for pharmaceutical companies, the Textbook of Clinical Trials, Second Edition appeals to those working in contract research organizations, medical departments and in the area of public health and health science alike.

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. Contents: The PastMedicinal Products: The Development ProcessClinical Trials: Design AspectsThe Rules and the RegsThe Ethical Pillars of Clinical ResearchThe Players Part I: Ethics Committee and Data Monitoring CommitteeThe Players Part II: The Sponsor and the Clinical Research OrganisationThe Players Part III: The Investigator, the Sub-Investigator and the Clinical Research CoordinatorThe Players Part IV: The Pharmacy and the Clinical LaboratoryThe Players Part V: The Subject or PatientSafety Assessment and MonitoringThe VisitsThe Essential Documents Part I: Before Study StartThe Essential Documents Part II: During Trial ConductThe Essential Documents Part III: After Completion or Termination of the TrialData ManagementA Special Case: Medical DevicesCompliance The Challenge of MonitoringThe Future of Clinical Trial Monitoring — Some Afterthoughts Readership: Clinical research monitors, clinical research associates, trial monitors, clinical research sponsors, contract research organizations (CROs), ethics committees, clinical investigators, and study nurses. Keywords: Clinical Research;Monitoring;CRA;GCP;Clinical Trials;Drug Development;Investigational Medicinal Products (IMPs)Review: Key Features: Current textbooks are US (FDA)-based, but this book covers the European situationProvides an up-to-date review of the theoretical and practical basis of clinical research monitoring and GCP, including the latest International Council for Harmonisation (ICH) GCP revisionsThe author has more than 10 years of experience in training and education of clinical research monitors

Clinical Research in Practice: A Guide for the Bedside Scientist is a straightforward guide to reading, evaluating, and using research in these clinical settings. The text helps the bedside scientist take a study from question to design to practice.

With his keen analytical mind and penchant for organization, Charles Darwin would have made an excellent clinical investiga-

tor. Unfortunately for surgery, his early exposure at Edinburgh to the brutality of operations in 1825 convinced him to reject his father's plan for his career and pursue his interest in nature. His subsequent observations of how environmental pressures shaped the development of new species provided the essential mechanism to explain evolution and the disappearance of those species that failed to adapt. Today, surgeons face the same reality as new technology, progressive regulation by government and payers, medico-legal risks, and public demands for proof of performance force changes in behavior that our predecessors never imagined. We know that surgeons have always prided themselves on accurate documentation of their results, including their complications and deaths, but observational studies involving a single surgeon or institution have given way to demands for controlled interventional trials despite the inherent difficulty of studying surgical patients by randomized, blinded techniques. That is why this book is so timely and important. In a logical and comprehensive approach, the authors have assembled a group of experienced clinical scientists who can demonstrate the rich variety of techniques in epidemiology and statistics for reviewing existing publications, structuring a clinical study, and analyzing the resulting data.

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 single trial is complex, with numerous regulations, administrative processes, medical procedures, deadlines and specific protocol instructions to follow. And yet, there has existed no single-volume, comprehensive clinical research reference manual for investigators, medical institutions, and national and international research personnel to keep on the shelf as a ready reference to navigate through trial complexities and ensure compliance with U.S. Federal Regulations and ICH GCP until The Sourcebook for Clinical Research. An actionable, step-by-step guide through beginning to advanced topics in clinical research with forms, templates and checklists to download from a companion website (https://www.elsevier.com/books-and-journals/book-companion/9780128162422), so that study teams will be compliant and will find all the necessary tools within this book. Moreover, The Sourcebook for Clinical Research contains clear information and guidance on the newest changes in the industry to keep seasoned investigators and staff current and compliant, in addition to providing detailed information regarding the most complex topics. This book serves as a quick, actionable, off-the-shelf resource to keep by your side at the medical clinic. Makes vital trial conduct information easy to understand and instructs on how to practically apply current Federal regulations and Good Clinical Practice (ICH GCP) Offers extensive guidance that is crucial for

guaranteeing compliance to clinical research regulations during each step of the clinical research process Provides up-to-date and extensive coverage of beginning to advanced topics, and, step-by-step actions to take during exceptional circumstances, including compassionate use, emergency use, human subjects protections for vulnerable populations, and federal audits Furnishes a detailed clinical research Glossary, and a comprehensive Appendix containing ready-to-use forms, templates, and checklists for clinical trial personnel to download and begin using immediately. Written for the fast-paced clinic environment with action steps and forms in the book to respond to a research subject's needs urgently and compliantly

This book is designed to meet the needs of both novice and senior researchers in Orthopaedics by providing the essential, clinically relevant knowledge on research methodology that is sometimes overlooked during training. Readers will find a wealth of easy-to-understand information on all relevant aspects, from protocol design, the fundamentals of statistics, and the use of computer-based tools through to the performance of clinical studies with different levels of evidence, multicenter studies, systematic reviews, meta-analyses, and economic health care studies. A key feature is a series of typical case examples that will facilitate use of the volume as a handbook for most common research approaches and study types. Younger researchers will also appreciate the guidance on preparation of abstracts, poster and paper presentations, grant applications, and publications. The authors are internationally renowned orthopaedic surgeons with extensive research experience and the book is published in collaboration with ISAKOS.

Complete evidence-based medical and surgical management of glaucoma for both the general ophthalmologist in practice and residents The only book that covers the new generation of glaucoma procedures including trabectome, trabecular bypass and canaloplasty, by the experts who developed them Includes the latest laser treatments for glaucoma including micro diode and titanium saphire trabeculoplasty as well as laser from an external approach The most comprehensive coverage of the optic nerve and the importance of nerve fiber layer hemorrhage Provides an integrated approach to neovascular glaucoma merging treatment to the retina, with the use of new anti-VEGF drugs, tubes, and shunts to achieve the best outcome Integrates clinical science with basic science to outline the next steps in glaucoma therapy

In an arena which has seen rapid change over the past decade, this work provides a comprehensive and up-to-date guide to the planning, organization and management of clinical trials.

Serving as an indispensable resource for students and general-interest readers alike, this three-volume work provides a comprehensive view of mental health that covers both mental well-being and mental illness. • Provides exhaustive content that affords readers a holistic understanding of mental health and mental disorders • Features extensive cross-referencing that allows readers to easily see connections and relationships between different entries • Offers end-of-entry further readings that serve as a gateway to additional information for study • Reflects on common perceptions and portrayals of mental health through a variety of pop culture-oriented entries that focus on subjects such as television shows and movies

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

"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 re-

lation 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.

In this fully revised and expanded fourth edition of the essential reference for clinical research coordinators, Deborrah Norris provides expanded coverage of CRC duties and regulatory requirements, including new sections on investigator responsibilities, data clarification, and adverse event reporting. The book s five appendices include a directory of CRC resources, updated forms and checklists, state regulatory requirements and contact information, conversion charts and tables, and a glossary.

This guidebook is filled with valuable information on the role and responsibilities of a clinical research coordinator (CRC) and explains the research process from the site and CRC perspective. Topics covered include: identifying the regulations governing clinical research; describing the drug development process; discussing good clinical practices and how to apply them in clinical trials and organizing a clinical practice.

This book is divided into 25 chapters covering more than 300 topics. This book will serve as a training guide to make your routine tasks more efficient, compliant and easy. After reading this book, Clinical Research Coordinators, clinical research personnel and aspirants would get: # Step by step in-depth training on roles and responsibilities of a clinical research coordinator before, during and after the completion of a clinical trial. # Discussion on day--to-day challenges and their solutions. # Training through real--time examples and ready-made checklists to conduct each activity more efficiently and correctly. # Guidance through strategies and measures to execute critical clinical trial activities. # Training on regulatory and ICH-GCP guidelines. # Tips on effective communication and coordination with site staff, investigator, sponsor, and IRB. # Assistance to become a better and successful clinical research coordinator. # Knowledge on other essential topics of clinical research.

What if you were suddenly in charge? After the initial excitement of a "battlefield promotion" wears off, you need to get in the trenches and get the job done. And if you are already in the trenches, you need quick access to information that will make your job easier. A comprehensive desk reference and guide, Clinical Studies Management: A Practical Guide to Success provides the practical skills and methods required by project managers running clinical studies. The author explains a framework for project management based on seven core themes: goals, budgets, time, resources, measurement, communication, and training. He solidly reviews how modern management theory can be brought to bear on the specialized demands of clinical trials. The book covers the practical how-tos of writing and costing a study, organizing an Investigator Meeting, and improving patient enrollment in your study. Divided into stand-alone chapters that make the information easy to find, the book presents a comprehensive overview of drug development processes and the trends that are driving change. If you are new to study management, the book rapidly brings you up to speed. If you are an experienced study manager, it gives you a convenient and authoritative reference you will use

on a daily basis. Whatever your level of experience, Clinical Studies Management: A Practical Guide to Success supplies the tools you need to manage your projects efficiently and effectively.

The Oxford Handbook of Clinical and Healthcare Research is a practical, concise, and easy-to-use reference for the full range of clinical and healthcare research topics, while incorporating evidence based medicine. Comprehensively providing a wide breadth of knowledge, this handbook clearly covers both the qualitative and quantitative aspects. This handbook includes clear instructions on the legislative requirements as well as the practical requirements of commissioning, conducting, analysing, and reporting research for those in clinical or healthcare practice, education or training. This book has been written with Good Clinical Practice (GCP) education in mind, giving valuable information needed for the accredited certificates and diploma-level benchmark exams now commonly required by employers. Whether you need practical advice on setting up and running a trial, negotiating regulations, learning vital research skills, or to study the underpinning concepts of research methods, this handbook will give you the vital information, clinical evidence, and guidance you need.

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.

Sugar chains (glycans) are often attached to proteins and lipids and have multiple roles in the organization and function of all organisms. "Essentials of Glycobiology" describes their biogenesis and function and offers a useful gateway to the understanding of glycans.

Publishing and Presenting Clinical Research, Fourth Edition is an excellent primer for investigators who wish to learn how to organize, present, and publish results of their research. Written by an experienced clinical researcher and editor, it uses hundreds of examples, tables and figures to show how to produce successful abstracts, posters, oral presentations, and manuscripts for publication. This book also serves as a companion to the popular text, Designing Clinical Research. This edition contains the latest: • Guidance on getting work accepted in medical journals and at scientific meetings • Examples of the do’s and don’ts of data presentation • Explanations of confusing statistical terminology • Templates to get started and avoid writers’ block • Tips for creating simple graphics and tables • Help for those who are not fluent in

English • Suggestions about getting the most from a poster session • Checklists for each section of a manuscript or presentation • Advice about authorship and responding to reviewers' comments Plus with this edition, there is access to a companion website with fully searchable text so you can access the content anytime, anywhere.

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

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.

Pediatric Inflammatory Bowel Disease, Second Edition provides an essential reference with an emphasis on the unique pediatric issues of IBD. Chapters focus on complications of IBD specific to children and adolescents. Treatment recommendations are based on the latest clinical research available. The textbook also presents sections dedicated to the aspects of participation in clinical research unique to children and adolescents and the complicated yet vital process of successfully transitioning a patient from a pediatric to adult specialist. Controversies in pediatric IBD care such as the off-label use of medications are also covered. The format incorporates multiple tables, graphs, and figures to improve readability and make for an efficient reference for clinicians to use. Thoroughly revised and updated from the first edition, the volumes includes new therapies that are currently being used or tested for treatment of IBD, important areas regarding incidence and prevalence, immunization and response to vaccine administration as well as advancements in our understanding of growth and development with particular to the use of growth hormone therapy. Other new areas covered include important topics of complementary and alternative medicine use in IBD, immunization, and liver disease in IBD. Pediatric Inflammatory Bowel Disease, Second Edition is a valuable resource for pediatric gastroenterologists as well as adult gastroenterologists.

In this revised third edition of the essential reference for clinical

research coordinators (CRCs), Deborrah Norris provides expanded coverage of CRC duties and regulatory requirements, including new sections on investigator responsibilities, data clarification, and adverse event reporting. The book's five appendices include a directory of CRC resources, updated forms and checklists, state regulatory requirements and contact information, conversion charts and tables, a glossary, and more.

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 novel and indispensable handbook for clinical research coordinators worldwide Because "saying isn't doing; doing is doing": This fourth volume in Mohit Bhandari's series of methodology books, conceived as a transformational guide to executing research for those who coordinate it on a daily basis, focuses not on the design of research projects, but rather on the actual execution of such projects. Key Features: International group of authors and practicing research coordinators with decades of collective hands-on experience Includes many crucial, but often neglected, topics such as principles of successful grant writing, working with study budgets, ethics and consent forms, regulatory versus standard trials, coordinating and conducting observational research and randomized clinical trials, and much more Many helpful templates and sample forms with checklists, consent forms, budget outlines, and more A broad readership including scientists, physicians, surgeons, epidemiologists and statisticians, and industry research and development directors will welcome this unique and valuable book. This book includes complimentary access to a digital copy on https://medone.thieme.com.