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This book aims to make the readers better informed and more critical consumers of clinical research. It will help the reader recognize the strengths and the weaknesses of scientific publications. In doing so, the reader will be able to distinguish patient-important and methodologically sound studies from those having limitations in design, conduct and interpretation. The text is basic and has no statistical formulas. Key take-home messages are listed at the end of each chapter. Cartoons make the text easier to read and generate a few laughs, and they underscore specific points, sometimes in a provocative way. In this Information Age, the practices of clinical medicine should no longer be based on what clinical doctors actively know. Rather, all of the importantly practice-relevant knowledge should not only already exist but also be codified in cyberspace, in directly practice-guiding 'expert systems' -- for the benefit of both doctors and patients everywhere. Each of these systems (discipline-

specific) would, prompted by a particular type of case presentation, present the doctor a questionnaire specific to cases of the type at issue, and document the doctor's answers to the questions. If at issue would be a case of complaint about a (particular type of) sickness, the system would translate the resulting diagnostic profile of the case into the corresponding probabilities of the illnesses to be considered. Similarly, if at issue would be an already-diagnosed case of a particular illness, the system would ask about, and record, the relevant elements in the prognostic profile of the case and then translate this profile into the probabilities of various outcomes to be considered, probabilities specific to the choice of treatment and prospective time in addition to that profile. And besides, these systems would analogously address the causal origin -- etiogenesis -- of cases of particular types of illness. While the requisite knowledge-base for these systems -- notably for the probabilities in them -- has not been addressed by such 'patient-oriented' clinical research as has been conducted (very extensively) up to now, this book delineates the nature of the suitably-transformed research (gnostic). The critically-transformative innovation in the research is the studies' focus on Gnostic Probability Functions -- dia-, etio-, and prognostic -- in the framework of logistic regression models. This book also presents a vision of how this critically-transformative research would most expeditiously be provided for and also conducted, among select sets of academic teaching hospitals. Data sharing can accelerate new discoveries by avoiding duplicative trials, stimulating new ideas for research, and enabling the maximal scientific knowledge and benefits to be gained from the efforts of clinical trial participants and investigators. At the same time, sharing clinical trial data presents risks, burdens, and challenges. These include the need to protect the privacy and honor the consent of clinical trial participants; safeguard the legitimate economic interests of sponsors; and guard against invalid secondary analyses, which could undermine trust in clinical trials or otherwise harm public health. Sharing Clinical Trial Data presents activities and strategies for the responsible sharing of clinical trial data.

With the goal of increasing scientific knowledge to lead to better therapies for patients, this book identifies guiding principles and makes recommendations to maximize the benefits and minimize risks. This report offers guidance on the types of clinical trial data available at different points in the process, the points in the process at which each type of data should be shared, methods for sharing data, what groups should have access to data, and future knowledge and infrastructure needs. Responsible sharing of clinical trial data will allow other investigators to replicate published findings and carry out additional analyses, strengthen the evidence base for regulatory and clinical decisions, and increase the scientific knowledge gained from investments by the funders of clinical trials. The recommendations of Sharing Clinical Trial Data will be useful both now and well into the future as improved sharing of data leads to a stronger evidence base for treatment. This book will be of interest to stakeholders across the spectrum of research--from funders, to researchers, to journals, to physicians, and ultimately, to patients. Cross-over trials are an important class of design used in the pharmaceutical industry and medical research, and their use continues to grow. Cross-over Trials in Clinical Research, Second Edition has been fully updated to include the latest methodology used in the design and analysis of cross-over trials. It includes more background material, greater coverage of important statistical techniques, including Bayesian methods, and discussion of analysis using a number of statistical software packages. * Comprehensive coverage of the design and analysis of cross-over trials. * Each technique is carefully explained and the mathematics is kept to a minimum. * Features many real and original examples, taken from the author's vast experience. * Includes discussion of analysis using SAS, S-Plus and, GenStat, StatXact and Excel. * Written in a style suitable for statisticians and physicians alike. * Computer programs to accompany the examples in the book can be downloaded from the Web Primarily aimed at statisticians and researchers working in the pharmaceutical industry, the book will also appeal to physicians involved in clinical research and

students of medical statistics. Strategy and Statistics in Clinical Trials is for all individuals engaged in clinical research, including professors, physicians, researchers in corporate and government laboratories, nurses, members of the allied health professions, and post-doctoral and graduate students who are potentially less exposed to understanding the pivotal role of statistics. . Enables nonstatisticians to better understand research processes and statistics' role in these processes . Offers real-life case studies and provides a practical, "how to" guide to biomedical R&D . Delineates the statistical building blocks and concepts of clinical trials . Promotes effective cooperation between statisticians and important other parties. There is growing recognition that the United States' clinical trials enterprise (CTE) faces great challenges. There is a gap between what is desired - where medical care is provided solely based on high quality evidence - and the reality - where there is limited capacity to generate timely and practical evidence for drug development and to support medical treatment decisions. With the need for transforming the CTE in the U.S. becoming more pressing, the IOM Forum on Drug Discovery, Development, and Translation held a two-day workshop in November 2011, bringing together leaders in research and health care. The workshop focused on how to transform the CTE and discussed a vision to make the enterprise more efficient, effective, and fully integrated into the health care system. Key issue areas addressed at the workshop included: the development of a robust clinical trials workforce, the alignment of cultural and financial incentives for clinical trials, and the creation of a sustainable infrastructure to support a transformed CTE. This document summarizes the workshop. Randomized clinical trials are the primary tool for evaluating new medical interventions. Randomization provides for a fair comparison between treatment and control groups, balancing out, on average, distributions of known and unknown factors among the participants. Unfortunately, these studies often lack a substantial percentage of data. This missing data reduces the benefit provided by the randomization and introduces potential biases in the comparison of the

treatment groups. Missing data can arise for a variety of reasons, including the inability or unwillingness of participants to meet appointments for evaluation. And in some studies, some or all of data collection ceases when participants discontinue study treatment. Existing guidelines for the design and conduct of clinical trials, and the analysis of the resulting data, provide only limited advice on how to handle missing data. Thus, approaches to the analysis of data with an appreciable amount of missing values tend to be ad hoc and variable. The Prevention and Treatment of Missing Data in Clinical Trials concludes that a more principled approach to design and analysis in the presence of missing data is both needed and possible. Such an approach needs to focus on two critical elements: (1) careful design and conduct to limit the amount and impact of missing data and (2) analysis that makes full use of information on all randomized participants and is based on careful attention to the assumptions about the nature of the missing data underlying estimates of treatment effects. In addition to the highest priority recommendations, the book offers more detailed recommendations on the conduct of clinical trials and techniques for analysis of trial data. READ ALL ABOUT IT! David Spiegelhalter has recently joined the ranks of Isaac Newton, Charles Darwin and Stephen Hawking by becoming a fellow of the Royal Society. Originating from the Medical Research Council ' s biostatistics unit, David has played a leading role in the Bristol heart surgery and Harold Shipman inquiries. Order a copy of this author ' s comprehensive text TODAY! The Bayesian approach involves synthesising data and judgement in order to reach conclusions about unknown quantities and make predictions. Bayesian methods have become increasingly popular in recent years, notably in medical research, and although there are a number of books on Bayesian analysis, few cover clinical trials and biostatistical applications in any detail. Bayesian Approaches to Clinical Trials and Health-Care Evaluation provides a valuable overview of this rapidly evolving field, including basic Bayesian ideas, prior distributions, clinical trials, observational studies, evidence synthesis and cost-

effectiveness analysis. Covers a broad array of essential topics, building from the basics to more advanced techniques. Illustrated throughout by detailed case studies and worked examples Includes exercises in all chapters Accessible to anyone with a basic knowledge of statistics Authors are at the forefront of research into Bayesian methods in medical research Accompanied by a Web site featuring data sets and worked examples using Excel and WinBUGS - the most widely used Bayesian modelling package Bayesian Approaches to Clinical Trials and Health-Care Evaluation is suitable for students and researchers in medical statistics, statisticians in the pharmaceutical industry, and anyone involved in conducting clinical trials and assessment of health-care technology. 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 medical 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. 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. 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 Edition 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. The Oxford Textbook of Clinical Research Ethics is the first comprehensive and systematic reference on clinical research ethics. Under the editorship of experts from the U.S. National Institutes of Health of the United States, the book's 73 chapters offer a wide-ranging and systematic examination of all aspects of research with human beings. Considering the historical triumphs of research as well as its tragedies, the textbook provides a framework for analyzing the ethical aspects of research studies with human beings. Through both conceptual analysis and systematic reviews of empirical data, the contributors examine issues ranging from scientific validity, fair subject selection, risk benefit ratio, independent review, and informed consent to focused consideration of international research ethics, conflicts of interests, and other aspects of responsible conduct of research. The editors of The Oxford Textbook of Clinical Research Ethics offer a work that critically assesses and advances scholarship in the field of human subjects research. Comprehensive in scope and depth, this book will be a crucial resource for researchers in the medical sciences, as well as teachers and students. "This book provides a practical guide to planning, tabulating, formulating, and implementing clinical research, in an easy-to-use, readable presentation"--Provided by publisher. 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. 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. A compilation of key clinical research topics where specific opinions and interpretations were done to bring light to the possible applications of clinical research rules and regulations. Each chapter has been carefully studied to present a clear idea of clinical trials issues and challenges, and how to meet them. Also the challenge to get a job in the clinical research market is discussed in detail in several chapters that will bring the reader a little closer to the clinical research industry.Topics like Clinical Research as a Career. How do You get that very First Job?, Catch 22-You Need Experience for Entry Level Clinical Research Jobs, What everybody should know about prescription drug safety, Mistakes to Avoid as a Clinical Trials Monitor, Big Mistakes in Clinical Trials Adverse Event Reporting, Who is really monitoring the clinical trial?, Everybody Should Know Before Going to a Job Interview, Clinical Research Training Accessibility among others are thoroughly

discussed. Clinical trials are an important part of medicine and healthcare today, deciding which treatments we use to treat patients. Anyone involved in healthcare today must know the basics of running and interpreting clinical trial data. Written in an easy-to-understand style by authors who have considerable expertise and experience in both academia and industry, Principles and Practice of Clinical Trial Medicine covers all of the basics of clinical trials, from legal and ethical issues to statistics, to patient recruitment and reporting results. Jargon-free writing style enables those with less experience to run their own clinical trials and interpret data Book contains an ideal mix of theory and practice so researchers will understand both the rationale and logistics to clinical trial medicine Expert authorship whose experience includes running clinical trials in an academic as well as industry settings Numerous illustrations reinforce and elucidate key concepts and add to the book's overall pedagogy 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 purpose of the book is to provide an overview of clinical research (types), activities, and areas where informatics and IT could fit into various activities and business practices. This book will introduce and apply informatics concepts only as they have particular relevance to clinical research settings. "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. 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. 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 In the realm of health care, privacy protections are needed to preserve patients' dignity and prevent possible harms. Ten years ago, to address these concerns as well as set guidelines for ethical health research, Congress called for a set of federal standards

now known as the HIPAA Privacy Rule. In its 2009 report, Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research, the Institute of Medicine's Committee on Health Research and the Privacy of Health Information concludes that the HIPAA Privacy Rule does not protect privacy as well as it should, and that it impedes important health research. It is increasingly important to examine the relationship between the outcomes of a clinical trial and the costs of the medical therapy under study. This book provides a practical guide to the techniques and issues involved in conducting economic evaluation in ongoing clinical trials, supported with examples. This book discusses ‘how’ to respectfully and responsibly include pregnant women in clinical research. In sharp contrast, the existing literature predominantly focuses on the reasons ‘why’ the inclusion of pregnant women in clinical research is necessary – viz., to develop effective treatments for women during pregnancy, to promote fetal safety, to reduce harm to women and fetuses from suboptimal care, and to allow access to the benefits of research participation. This book supports the shift to a new default position, whereby pregnant women are included in clinical research unless researchers argue convincingly for their exclusion. This shift raises many as yet unexplored ethical and policy questions about existing barriers to the equitable inclusion of pregnant women in research. This book is original in three key ways. First, it presents an unparalleled depth of analysis of the ethics of research with pregnant women, bringing together many of the key authors in this field as well as experts in research ethics and in vulnerability who have not previously applied their work to pregnant women. Second, it includes innovative theoretical work in ethics and disease specific case studies that highlight the current complexity and future challenges of research involving pregnant women. Third, the book brings together authors who argue both for and against including more pregnant women in formal clinical trials. A complete guide to understanding and applying clinical research results Ideal for both researchers and healthcare providers Understanding

Clinical Research addresses both the operational challenges of clinical trials and the needs of clinicians to comprehend the nuances of research methods to accurately analyze study results. This timely resource covers all aspects of clinical trials--from study design and statistics to regulatory oversight--and it delivers a detailed yet streamlined overview of must-know research topics. The text features an accessible three-part organization that traces the evolution of clinical research and explains the bedrock principles and unique challenges of clinical experimentation and observational research. Reinforcing this content are real-life case examples--drawn from the authors' broad experience--that put chapter concepts into action and contribute to a working knowledge of integral research techniques. FEATURES: The most definitive guide to promoting excellence in clinical research, designed to empower healthcare providers to assess a study's strengths and weaknesses with confidence and apply this knowledge to optimize patient outcomes In-depth coverage of fundamental research methods and protocols from preeminent authorities provides readers with an instructive primer and a springboard for ongoing clinical research education Clear, comprehensive three-part organization: Section One: Evolution of Clinical Research offers a succinct history of clinical trials, drug regulations, and the role of the FDA while covering the impact of information technology and academic research organizations Section Two: Principles of Clinical Experimentation takes you through the typical phases of clinical trials in the development of medical products, from initial human subject research to postapproval surveillance studies Section Three: Observational Research highlights the underlying principles, pitfalls, and methods for case-control studies, cohort studies, registries, and subgroup analyses within randomized trials 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 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. 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. In its extensively revised and updated Second Edition, this book provides a solid foundation for readers interested in clinical research. Discussion encompasses genetic, pharmacoepidemiologic and implementation research. All chapters have been updated with new information and many new tables have been added to elucidate key

points. The book now offers discussion on how to handle missing data when analyzing results, and coverage of Adaptive Designs and Effectiveness Designs and new sections on Comparative Effectiveness Research and Pragmatic Trials. Chapter 6 includes new material on Phase 0 Trials, expanded coverage of Futility Trials, a discussion of Medical Device approval, Off Label Drug use and the role of the FDA in regulating advertising. Additional new information includes the role of pill color and shape in association with the placebo effect and an examination of issues surrounding minority recruitment. The final chapter offers a new section on manuscript preparation along with a discussion of various guidelines being adopted by journals: CONSORT, STROBE, PRISMA, MOOSE and others; and coverage of Conflicts of Interest, Authorship, Coercive Citation, and Disclosures in Industry-Related Associations. Building on the strengths of its predecessor in its comprehensive approach and authoritative advice, the new edition offers more of what has made this book a popular, trusted resource for students and working researchers alike. Despite their effectiveness in the evaluation of new pharmacological compounds, controlled clinical trials are sometimes inadequate. Using data from the literature as well as from the author's own experience with clinical trials, Human Experimentation: Methodologic Issues Fundamental to Clinical Trials addresses such inadequacies and tries to provide solutions. This work is the first to thoroughly examine these unsolved inadequacies and problems with the design and the execution of clinical trials and, more importantly, to provide solutions for these problems. It is important for anyone who is involved in clinical research: clinicians, pharmacists, biochemists, statisticians, nurses, sponsors, etc., and anyone who is involved in applying results of research to patients, i.e. physicians. This handbook is a definitive, up-to-date, and succinct text covering the legislative requirements, scientific foundations, and clinical good practice necessary for clinical, academic, and healthcare research. Clinical Research Computing: A Practitioner ’ s Handbook deals with the nuts-and-bolts of providing informatics and computing support for

clinical research. The subjects that the practitioner must be aware of are not only technological and scientific, but also organizational and managerial. Therefore, the author offers case studies based on real life experiences in order to prepare the readers for the challenges they may face during their experiences either supporting clinical research or supporting electronic record systems. Clinical research computing is the application of computational methods to the broad field of clinical research. With the advent of modern digital computing, and the powerful data collection, storage, and analysis that is possible with it, it becomes more relevant to understand the technical details in order to fully seize its opportunities. Offers case studies, based on real-life examples where possible, to engage the readers with more complex examples Provides studies backed by technical details, e.g., schema diagrams, code snippets or algorithms illustrating particular techniques, to give the readers confidence to employ the techniques described in their own settings Offers didactic content organization and an increasing complexity through the chapters Ethical Considerations When Preparing a Clinical Research Protocol, Second Edition, provides a foundation for improving skills in the understanding of ethical requirements in the design and conduct of clinical research. It includes practical information on ethical principles in clinical research, how to design appropriate research studies, how to consent and assent documents, how to get protocols approved, special populations, confidentiality issues, and the reporting of adverse events. The book's valuable appendix includes a listing of web resources about research ethics, along with a glossary, making it an invaluable resource for scientists collaborating in clinical trials, physician investigators, clinical research fellows, and more. Walks investigators and trainees through the identification of the ethical aspects of each section of a clinical research protocol Includes case histories that illustrate key points Contains information on conducting clinical research within the pharmaceutical industry Includes internet resources and worldwide web addresses for important research ethics documents and regulations

Contains a chapter on Study Design and Methodology that is purposely expanded to explicitly address biostatistical considerations 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 majority of physicians are poorly knowledgeable about statistics and research design, yet are expected to do clinical research and write articles (if in academia) or, at the very least, to read the literature critically and provide evidence-based care to patients. The basic skills involved are touched on very minimally in residency, but not in enough depth for an untrained investigator to successfully design or conduct a study, or analyze research findings in any meaningful way. This volume is intended as a “ quick fix ” , allowing readers to look up information rapidly about various design types and statistical methods to see what the pros, cons, and indications for each are. Research implementation, including regulatory issues and grant writing, is also covered. The book is unique in physical medicine and rehabilitation, and with the increased emphasis on outcomes measurement and push toward a national agenda for disability research, will appeal both to investigators planning and executing studies and clinicians looking to better understand how the findings impact their practice. A list of topics with an outline of headings for each of the

sections is attached. In recent decades, advances in biomedical research have helped save or lengthen the lives of children around the world. With improved therapies, child and adolescent mortality rates have decreased significantly in the last half century. Despite these advances, pediatricians and others argue that children have not shared equally with adults in biomedical advances. Even though we want children to benefit from the dramatic and accelerating rate of progress in medical care that has been fueled by scientific research, we do not want to place children at risk of being harmed by participating in clinical studies. Ethical Conduct of Clinical Research Involving Children considers the necessities and challenges of this type of research and reviews the ethical and legal standards for conducting it. It also considers problems with the interpretation and application of these standards and conduct, concluding that while children should not be excluded from potentially beneficial clinical studies, some research that is ethically permissible for adults is not acceptable for children, who usually do not have the legal capacity or maturity to make informed decisions about research participation. The book looks at the need for appropriate pediatric expertise at all stages of the design, review, and conduct of a research project to effectively implement policies to protect children. It argues persuasively that a robust system for protecting human research participants in general is a necessary foundation for protecting child research participants in particular. This is a comprehensive major reference work for our SpringerReference program covering clinical trials. Although the core of the Work will focus on the design, analysis, and interpretation of scientific data from clinical trials, a broad spectrum of clinical trial application areas will be covered in detail. This is an important time to develop such a Work, as drug safety and efficacy emphasizes the Clinical Trials process. Because of an immense and growing international disease burden, pharmaceutical and biotechnology companies continue to develop new drugs. Clinical trials have also become extremely globalized in the past 15 years, with over 225,000 international trials ongoing at this point in time.

Principles in Practice of Clinical Trials is truly an interdisciplinary that will be divided into the following areas: 1) Clinical Trials Basic Perspectives 2) Regulation and Oversight 3) Basic Trial Designs 4) Advanced Trial Designs 5) Analysis 6) Trial Publication 7) Topics Related Specific Populations and Legal Aspects of Clinical Trials The Work is designed to be comprised of 175 chapters and approximately 2500 pages. The Work will be oriented like many of our SpringerReference Handbooks, presenting detailed and comprehensive expository chapters on broad subjects. The Editors are major figures in the field of clinical trials, and both have written textbooks on the topic. There will also be a slate of 7-8 renowned associate editors that will edit individual sections of the Reference. Pharmaceutical companies, academic researchers, and government agencies such as the Food and Drug Administration and the National Institutes of Health all possess large quantities of clinical research data. If these data were shared more widely within and across sectors, the resulting research advances derived from data pooling and analysis could improve public health, enhance patient safety, and spur drug development. Data sharing can also increase public trust in clinical trials and conclusions derived from them by lending transparency to the clinical research process. Much of this information, however, is never shared. Retention of clinical research data by investigators and within organizations may represent lost opportunities in biomedical research. Despite the potential benefits that could be accrued from pooling and analysis of shared data, barriers to data sharing faced by researchers in industry include concerns about data mining, erroneous secondary analyses of data, and unwarranted litigation, as well as a desire to protect confidential commercial information. Academic partners face significant cultural barriers to sharing data and participating in longer term collaborative efforts that stem from a desire to protect intellectual autonomy and a career advancement system built on priority of publication and citation requirements. Some barriers, like the need to protect patient privacy, pre- sent challenges for both sectors. Looking

ahead, there are also a number of technical challenges to be faced in analyzing potentially large and heterogeneous datasets. This public workshop focused on strategies to facilitate sharing of clinical research data in order to advance scientific knowledge and public health. While the workshop focused on sharing of data from preplanned interventional studies of human subjects, models and projects involving sharing of other clinical data types were considered to the extent that they provided lessons learned and best practices. The workshop objectives were to examine the benefits of sharing of clinical research data from all sectors and among these sectors, including, for example: benefits to the research and development enterprise and benefits to the analysis of safety and efficacy. Sharing Clinical Research Data: Workshop Summary identifies barriers and challenges to sharing clinical research data, explores strategies to address these barriers and challenges, including identifying priority actions and "low-hanging fruit" opportunities, and discusses strategies for using these potentially large datasets to facilitate scientific and public health advances.