Basic Principles Of Clinical Research And Methodology 1st Edition

Now updated with new data and examples throughout, Clinical Epidemiology: Principles, Methods, and Applications for Clinical Research, Second Edition is a comprehensive resource that introduces the reader to the basics of clinical epidemiology and explores the principles and methods that can be used to obtain quantitative evidence on the effects of interventions and on the diagnosis, etiology, and prognosis of disease. The everyday challenges of clinical research and the quantitative knowledge required to practice medicine are also examined, making this book a valuable reference for both graduate and undergraduate students in medicine and related disciplines, as well as for professionals involved in the design and conduct of clinical research.

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

Basic Principles of Clinical Research and MethodologyJaypee Brothers,Medical Publishers Pvt. LimitedPrinciples and Practice of Clinical ResearchElsevier

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.

Clinical Epidemiology

Basic Principles and Clinical Applications

Principles and Methods

Discussion Framework for Clinical Trial Data Sharing

Principles of Research Methodology

Basic Principles and Clinical Application

This is the first comprehensive guide to the design of behavioral randomized clinical trials (RCT) for chronic diseases. It includes the scientific foundations for behavioral trial methods, problems that have been encountered in past behavioral trials, advances in design that have evolved, and promising trends and opportunities for the future. The value of this book lies in its potential to foster an ability to speak the language of medicine through conduct of high-quality behavioral clinical trials that match the rigor commonly seen in double-blind drug trials. It is relevant for testing any treatment aimed at improving a behavioral, social, psychosocial, environmental, or policy-level risk factor for a chronic disease including, for example, obesity, sedentary behavior, adherence to treatment, psychosocial stress, food deserts, and fragmented care. Outcomes of interest are those that are of clinical significance in the treatment of chronic diseases, including standard risk factors such as cholesterol, blood pressure, and glucose, and clinical outcomes such as hospitalizations, functional limitations, excess morbidity, quality of life, and mortality. This link between behavior and chronic disease requires innovative clinical trial methods not only from the behavioral sciences but also from medicine, epidemiology, and biostatistics. This integration does not exist in any current book, or in any training program, in either the behavioral sciences or medicine.

The Drug Discovery and Clinical Research bandwagon has been joined by scientists and researchers from all fields including basic sciences, medical sciences, biophysicists, biotechnologists, statisticians, regulatory officials and many more. The joint effort and contribution from all is translating into the fast development of this multi-faceted field. At the same time, it has become challenging for all stakeholders to keep abreast with the explos information. The race for the finish-line leaves very little time for the researchers to update themselves and keep tabs on the latest developments in the industry. To meet these challenges, this book entitled Drug Discovery and Clinical Research has been compiled. All chapters have been written by stalwarts of the field who have their finger on the pulse of the industry. The aim of the book is to provide succinctly within one cover, an update aspects of this wide area. Although each of the chapter dealt here starting from drug discovery and development, clinical development, bioethics, medical devices, pharmacovigilance, data management, safety monitoring, patient recruitment, etc. are topics for full-fledged book in themselves, an effort has been made via this book to provide a bird's eye view to readers and help them to keep abreast with the latest development despite const time. It is hoped that the book will contribute to the growth of readers, which should translate into drug discovery and clinical research industry's growth.

Principles of Research Design and Drug Literature Evaluation is a unique resource that provides a balanced approach covering critical elements of clinical research, biostatistical principles, and scientific literature evaluation techniques for evidence-based medicine. This accessible text provides comprehensive course content that meets and exceeds the curriculum standards set by the Accreditation Council for Pharmacy Education (ACPE). Written by expert authors specializing in pharmacy practice and research, this valuable text will provide pharmacy students and practitioners with a thorough understanding of the principles and practices of drug literature evaluation with a strong grounding in research and biostatistical principles. Principles of Research Design and Drug Literature Evaluation is an ideal foundation for professional pharmacy students and a key resource for pharmacy residents, research fellows, practitioners, and clinical researchers. FEATURES * Chapter Pedagogy: Learning Objectives, Review Questions, References, and Online Resources * Instructor Resources: PowerPoint Presentations, Test Bank, and an Answer Key * Student Resources: a Navigate Companion Website, including Crossword Puzzles, Interactive Flash Cards, Interactive Glossary, Matching Questions, and Web Links Fr

Foreword: "This book was designed to provide and encourage practitioner's development and use of critical drug information evaluation skills through a deeper understanding of the foundational principles of study design and statistical methods. Because guidance on how a study's limited findings should not be used is rare, practitioners must understand and evaluate for themselves the veracity and implications of the inherently limited prima literature findings they use as sources of drug information to make evidence-based decisions together with their patients. The editors organized the book into three supporting sections to meet their pedagogical goals and address practitioners' needs in translating research into practice. Thanks to the editors, authors, and content of this book, you can now be more prepared than ever before for translating research into practice." L. Douglas P PhD, FAPhA Editor-in-Chief Emeritus, Journal of the American Pharmacists Association Professor and Associate Dean for Academic Affairs, College of Pharmacy, University of Texas at Tyler, Tyler, Texas

Principles of Translational Science in Medicine: From Bench to Bedside, Third Edition, provides an update on major achievements in the translation of research into medically relevant results and therapeutics. The book presents a thorough discussion of biomarkers, early human trials, and networking models, and includes institutional and industrial support systems. It also covers algorithms that have influenced all major areas of biomedical research in recent years, resulting in an increasing number of new chemical/biological entities (NCEs or NBEs) as shown in FDA statistics. New chapters include: Translation in Oncology, Biologicals, and Orphan Drugs. The book is ideal for use as a guide for biomedical scientists to establish a systematic approach to translational medicine and is written by worldwide experts in their respective fields. Includes state-of-the-art principles, tools as biomarkers and early clinical trials, algorithms of translational science in medicine Provides in-depth description of special translational aspects in the currently most successful areas of clinical translation, namely oncology and immunology Covers status of institutionalization of translational medicine, networking structures and outcomes at the level of marketing authorization

The Belmont report

Principles and Practice of Clinical Trials

Principles of Clinical Research

Principles and Practice of Clinical Trial Medicine

Scientific Foundations

Surgical Research

Statistical Design, Monitoring, and Analysis of Clinical Trials, Second Edition concentrates on the biostatistics component of clinical trials. This new edition is updated throughout and includes five new chapters. Developed from the authors' courses taught to public health and medical students, residents, and fellows during the past 20 years, the text shows how biostatistics in clinical trials is an integration of many fundamental scientific princip

The book begins with ethical and safety principles, core trial design concepts, the principles and methods of sample size and power calculation, and analysis of covariance and stratified analysis. It then focuses on sequential designs and methods for two-stage Phase II cancer trials to Phase III group sequential trials, covering monitoring safety, futility, and efficacy. The authors also discuss the development of sample size reestimation and a procedures, phase 2/3 seamless design and trials with predictive biomarkers, exploit multiple testing procedures, and explain the concept of estimand, intercurrent events, and different missing data processes, and describe how to analyze incomplete data by proper multiple imputations. This text reflects the academic research, commercial development, and public health aspects of clinical trials. It gives students and practitioners a multidisc concepts and techniques involved in designing, monitoring, and analyzing various types of trials. The book's balanced set of homework assignments and in-class exercises are appropriate for students and researchers in (bio)statistics, epidemiology, medicine, pharmacy, and public health.

Clinical and Translational Science: Principles of Human Research, Second Edition, is the most authoritative and timely resource for the broad range of investigators taking on the challenge of clinical and translational science, a field that is devoted to investigating human health and disease, interventions, and outcomes for the purposes of developing new treatment approaches, devices, and modalities to improve health. This updated second an international perspective, beginning with fundamental principles, experimental design, epidemiology, traditional and new biostatistical approaches, and investigative tools. It presents complete instruction and guidance from fundamental principles, approaches, and infrastructure, especially for human genetics and genomics, human pharmacology, research in special populations, the societal context of human research, and the future of hu on to discuss legal, social, and ethical issues, and concludes with a discussion of future prospects, providing readers with a comprehensive view of this rapidly developing area of science. Introduces novel physiological and therapeutic strategies for engaging the fastest growing scientific field in both the private sector and academic medicine Brings insights from international leaders into the discipline of clinical and translational science Addr repurposing and development, innovative and improved approaches to go/no-go decisions in drug development, and traditional and innovative clinical trial designs

It is a natural phenomenon for all living organisms in the world to undergo different kinds of stress during their life span. Stress has become a common problem for human beings in this materialistic world. In this period, a publication of any material on stress will be helpful for the human society. The book Basic Principles and Clinical Significance of Oxidative Stress targets all aspects of oxidative stress, including principles, mechanisms, and book covers four sections: Free Radicals and Oxidative Stress, Natural Compounds as Antioxidants, Antioxidants - Health and Disease, and Oxidative Stress and Therapy. Each of these sections is interwoven with the theoretical aspects and experimental techniques of basic and clinical sciences. This book will be a significant source to scientists, physicians, healthcare professionals, and students who are interested in exploring the effect o

This expanded third edition provides an introduction to the conduct of clinical research as well as more comprehensive and expansive content about the infrastructure necessary for a successful clinical research organization or enterprise. With authors who are experts in clinical research in both the public and private sectors, this publication provides essential information to clinical investigators who wish to develop and conduct well designed protocols that comply with rigorous study design, ethical, and regulatory requirements.

Allergy and Sleep

Behavioral Clinical Trials for Chronic Diseases

Understanding Clinical Research

Principles of Clinical Cancer Research

Basic Principles Of Clinical Research

Pharmacoepidemiology

The 2014â€"2015 Ebola epidemic in western Africa was the longest and most deadly Ebola epidemic in history, resulting in 28,616 cases and 11,310 deaths in Guinea, Liberia, and Sierra Leone. The Ebola virus has been known since 1976, when two separate outbreaks were identified in the Democratic Republic of Congo (then Zaire) and South Sudan (then Sudan). However, because all Ebola outbreaks prior to that in West Africa in 2014â€"2015 were relatively isolated and of short duration, little was known about how to best manage patients to improve survival, and there were no approved therapeutics or vaccines. When the World Heath Organization declared the 2014-2015 epidemic a public health emergency of international concern in August 2014, several teams began conducting formal clinical trials in the Ebola affected countries during the outbreak. Integrating Clinical Research into Epidemic Response: The Ebola Experience assesses the value of the clinical trials held during the 2014â€"2015 epidemic and makes recommendations about how the conduct of trials could be improved in the context of a future international emerging or re-emerging infectious disease events.

Part of "RPS Pharmacy Business Administration Series", this book offers good clinical practice guidelines. It includes standards on how clinical trials should be conducted, provide assurance of safety and efficacy of various drugs and protect human rights.

Functional magnetic resonance imaging (fMRI) measures quick, tiny metabolic changes that take place in the brain, providing the most sensitive method currently available for identifying, investigating, and monitoring brain tumors, stroke, and chronic disorders of the nervous system like multiple sclerosis, and brain abnormalities related to dementia or seizures. This overview explores experimental research design, outlines challenges and limitations of fMRI, provides a detailed neuroanatomic atlas, and describes clinical applications of fMRI in cognitive, sensory, motor, and pharmacological cases, translating research into clinical application.

The randomized control clinical trial has become the gold standard scientific method for the evaluation of pharmaceuticals, biologics, devices, procedures and diagnostic tests. This trial design has been successfully used in both therapeutic and disease prevention trials. It is superior to alternative designs by eliminating several sources of bias which exist in those designs. This role has evolved over the past three decades in a number of disease areas including cardiology, opthalmology, cancer and AIDS. While the specifics of using the randomized control design for a specific intervention and disease may differ, the basic fundamentals still apply in developing the study protocol and operational procedures. These fundamentals still apply in developing the study protocol and operational procedures. These fundamentals include identifying the specific questions to be tested and appropriate outcome measures, determining an adequate sample size, specifying the randomization procedure, detailing the intervention with visit schedules for subject evaluation, establishing an interim data and safety monitoring plan, detailing the final analysis plan and determining the organizational structure.This text is structured to address the fundamentals as the protocol for a clinical trial is being developed. A chapter is devoted to each of the critical areas of a protocol to aid the clinical trial researcher. The fundamentals described in this text are based on sound scientific methodology, statistical principles and years of accumulated experience by the three authors. Collectively, the authors have been active researchers in a broad area of clinical trials including cardiology, cancer, opthalmology, diabetes, osteoporosis, AIDS, women's health and screening tests. In these studies, the authors have served as members of the steering committee responsible for developing the protocol and as members of data and safety monitoring committees. The fundamentals were proposed in the first edition published in 1981 and have not changed substantially in the later editions. However, the number of examples illustrating the fundamentals has greatly expanded base on the collective experience of the authors.This text is intended for the clinical researcher who is interested in designing a clinical trial and developing a protocol. It is also of value to researchers and practitioners who must critically evaluate the literature of published clinical trials and assess the merits of each trial and the implications for the care and treatment of patients. The test uses numerous examples of published clinical trials from a variety of medical disciples to meaningfully illustrate the fundamentals. Technical design issues such as sample size are considered but the technical details have been suppressed as much as possible through the use of graphs and tables. While the technical material has been kept to a minimum, the statistician may still find the principles and fundamentals presented in this text useful both in a consulting and teaching capacity.The text assumes that the readers have only a modest formal statistical background. A basic introductory statistics course is helpful in maximizing the benefit of the text. However, a researcher or practitioner with no statistical background would still find most, if not all the chapters understandable and useful.

Maximizing Benefits, Minimizing Risk

Principles of Translational Science in Medicine

Basic Principles of Drug Discovery and Development

A Guide for Clinical Investigators

Integrating Clinical Research into Epidemic Response

Developing a National Registry of Pharmacologic and Biologic Clinical Trials

Principles of Clinical Cancer Research provides comprehensive coverage of the fundamentals of clinical cancer research, including the full spectrum of methodologies used in the field. For those involved in research or considering research careers, this book offers a mix of practical advice and analytical tools for effective training in theoretical principles as well as specific, usable teaching examples. The clinical oncologist or trainee will find a high-yield, practical guide to the interpretation of the oncology literature and the application of data to real-world settings. Valuable for both researchers and clinicians who wish to sharpen their skills, this book contains all of the cornerstones and explanations needed to produce and recognize quality clinical science in oncology. Written from the physician-scientist's perspective, the book lays a strong foundation in preclinical sciences that is highly relevant to careers in translational oncology research along with coverage of population and outcomes research and clinical trials. It brings together fundamental principles in oncology with the statistical concepts one needs to know to design and interpret studies successfully. With each chapter including perspectives of both clinicians and scientists or biostatisticians, Principles of Clinical Cancer Research provides balanced, instructive, and high-quality topic overviews and applications that are accessible and thorough for anyone in the field. KEY FEATURES: Gives real-world examples and rationales behind which research methods to use when and why Includes numerous tables featuring key statistical methods and programming commands used in everyday clinical research Contains illustrative practical examples and figures in each chapter to help the reader master concepts Provides tips and pointers for structuring a career, avoiding pitfalls, and achieving success in the field of clinical cancer research Access to fully downloadable eBook

Sharing data generated through the conduct of clinical trials offers the promise of placing evidence about the safety and efficacy of therapies and clinical interventions on a firmer basis and enhancing the benefits of clinical trials. Ultimately, such data sharing - if carried out appropriately - could lead to improved clinical care and greater public trust in clinical research and health care. "Discussion Framework for Clinical Trial Data Sharing: Guiding Principles, Elements, and Activities" is part of a study of how data from clinical trials might best be shared. This document is designed as a framework for discussion and public comment. This framework is being released to stimulate reactions and comments from stakeholders and the public. The framework summarizes the committee's initial thoughts on guiding principles that underpin responsible sharing of clinical trial data, defines key elements of clinical trial data and data sharing, and describes a selected set of clinical trial data sharing activities.

A unique reference manual for academic surgeons, this book discusses every facet of surgical research. From getting grant money to choosing a topic, reviewing the literature, planning and conducting research, and reporting results.

Atkinson's Principles of Clinical Pharmacology, Fourth Edition is the essential reference on the pharmacologic principles underlying the individualization of patient therapy and contemporary drug development. This well-regarded survey continues to focus on the basics of clinical pharmacology for the development, evaluation and clinical use of pharmaceutical products while also addressing the most recent advances in the field. Written by leading experts in academia, industry, clinical and regulatory settings, the fourth edition has been thoroughly updated to provide readers with an ideal reference on the wide range of important topics impacting clinical pharmacology. Presents the essential knowledge for effective practice of clinical pharmacology Includes a new chapter and extended discussion on the role of personalized and precision medicine in clinical pharmacology Offers an extensive regulatory section that addresses US and international issues and guidelines Provides extended coverage of earlier chapters on transporters, pharmacogenetics and biomarkers, along with further discussion on "Phase 0" studies (microdosing) and PBPK

Fundamental Principles of Clinical Reasoning & Research

The Ebola Experience

Basic Science Methods for Clinical Researchers

Clinical Epidemiology & Evidence-Based Medicine

Ethical Principles for Medical Research Involving Human Subjects

Designing Clinical Research

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 classic, field-defining textbook, now in its sixth edition, provides the most comprehensive guidance available for anyone needing up-to-date information in pharmacoepidemiology. This edition has been fully revised and updated throughout and continues to provide a rounded view on all perspectives from academia, industry and regulatory bodies, addressing data sources, applications and methodologies with great clarity.

This unique textbook integrates statistical concepts into evidence-based clinical practice and patient management. Research concepts and techniques are drawn from epidemiology, bio-statistics, and psychometrics, as well as educational and social science research. Clinical examples throughout the text illustrate practical and scientifically sound applications of the concepts. Data tables and research vignettes highlight statistical distributions involving probability. Methods to locate and utilize web-based information relevant to clinical research are discussed, and web URLs are provided. Further learning is encouraged by the inclusion of suggested activities, recommended readings, references, and a comprehensive glossary of research terms. Additional resources are available at a Connection Website, connection.LWW.com/go/stommel.

Principles of Research Methodology: A Guide for Clinical Investigators is the definitive, comprehensive guide to understanding and performing clinical research. Designed for medical students, physicians, basic scientists involved in translational research, and other health professionals, this indispensable reference also addresses the unique challenges and demands of clinical research and offers clear guidance in becoming a more successful member of a medical research team and critical reader of the medical research literature. The book covers the entire research process, beginning with the conception of the research problem to publication of findings. Principles of Research Methodology: A Guide for Clinical Investigators comprehensively and concisely presents concepts in a manner that is relevant and engaging to read. The text combines theory and practical application to familiarize the reader with the logic of research design and hypothesis construction, the importance of research planning, the ethical basis of human subjects research, the basics of writing a clinical research protocol and scientific paper, the logic and techniques of data generation and management, and the fundamentals and implications of various sampling techniques and alternative statistical methodologies. Organized in thirteen easy to read chapters, the text emphasizes the importance of clearly-defined research questions and well-constructed hypothesis (reinforced throughout the various chapters) for informing methods and in guiding data interpretation. Written by prominent medical scientists and methodologists who have extensive personal experience in biomedical investigation and in teaching key aspects of research methodology to medical students, physicians and other health professionals, the authors expertly integrate theory with examples and employ language that is clear and useful for a general medical audience. A major contribution to the methodology literature, Principles of Research Methodology: A Guide for Clinical Investigators is an authoritative resource for all individuals who perform research, plan to perform it, or wish to understand it better.

Guiding Principles, Elements, and Activities

Fundamentals of Clinical Trials

Women and Health Research

Workshop Report

Clinical and Translational Science

Principles of Human Research

Basic Principles of Drug Discovery and Development presents the multifaceted process of identifying a new drug in the modern era, which requires a multidisciplinary team approach with input from medicinal chemists, biologists, pharmacologists, drug metabolism experts, toxicologists, clinicians, and a host of experts from numerous additional fields. Enabling technologies such as high throughput screening, structure-based drug design, molecular modeling, pharmaceutical profiling, and translational medicine are critical to the successful development of marketable therapeutics. Given the wide range of disciplines and techniques that are required for cutting edge drug discovery and development, a scientist must master their own fields as well as have a fundamental understanding of their collaborator ' s fields. This book bridges the knowledge gaps that invariably lead to communication issues in a new scientist ' s early career, providing a fundamental understanding of the various techniques and disciplines required for the multifaceted endeavor of drug research and development. It provides students, new industrial scientists, and academics with a basic understanding of the drug discovery and development process. The fully updated text provides an excellent overview of the process and includes chapters on important drug targets by class, in vitro screening methods, medicinal chemistry strategies in drug design, principles of in vivo pharmacokinetics and pharmacodynamics, animal models of disease states, clinical trial basics, and selected business aspects of the drug discovery process. Provides a clear explanation of how the pharmaceutical industry works, as well as the complete drug discovery and development process, from obtaining a lead, to testing the bioactivity, to producing the drug, and protecting the intellectual property Includes a new chapter on the discovery and development of biologics (antibodies proteins, antibody/receptor complexes, antibody drug conjugates), a growing and important area of the pharmaceutical industry landscape Features a new section on formulations, including a discussion of IV formulations suitable for human clinical trials, as well as the application of nanotechnology and the use of transdermal patch technology for drug delivery Updated chapter with new case studies includes additional modern examples of drug discovery through high through-put screening, fragment-based drug design, and computational chemistry

Clinical research is about the drug development it involves selection of multiple molecules with screening of each drug molecule and selecting the appropriate drug with respect to study. The book details about steps involved in clinical research and drug selection. Clinical trial is a broad branch of clinical research, which includes preparation, planning and documentation for initiation of clinical trials. In this book different steps are elaborated in form of different chapters. This book will brief students about the process of marketing, selection of drugs, case report form, communication between the stakeholders and results.

In the nineteenth century some scientists argued that women should not be educated because thinking would use energy needed by the uterus for reproduction. The proof? Educated women had a lower birth rate. Today's researchers can only shake their heads at such reasoning. Yet professional journals and the popular press are increasingly criticizing medical research for ignoring women's health issues. Women and Health Research examines the facts behind the public's perceptions about women participating as subjects in medical research. With the goal of increasing researchers' awareness of this important topic, the book explores issues related to maintaining justice (in its ethical sense) in clinical studies. Leading experts present general principles for the ethical conduct of research on women â €"principles that are especially important in the light of recent changes in federal policy on the inclusion of women in clinical research. Women and Health Research documents the historical shift from a paternalistic approach by researchers toward women and a disproportionate reliance on certain groups for research to one that emphasizes proper access for women as subjects in clinical studies in order to ensure that women receive the benefits of research. The book addresses present-day challenges to equity in four areas: Scientific â €"Do practical aspects of scientific research work at cross-purposes to gender equity? Focusing on drug trials, the authors identify rationales for excluding people from research based on demographics. Social and Ethical â €"The authors offer compelling discussions on subjectivity in science, the evidence for male bias, and issues related to race and ethnicity, as well as the recruitment, retention, and protection of research participants. Legal â €"Women and Health Research reviews federal research policies that affect the inclusion of women and evaluates the basis for researchers' fears about liability, citing court cases. Risk â €"The authors focus on risks to reproduction and offspring in clinical drug trials, exploring how risks can be identified for study participants, who should make the assessment of risk and benefit for participation in a clinical study, and how legal implications could be addressed. This landmark study will be of immediate use to the research community, policymakers, women's health advocates, attorneys, and individuals.

To improve public confidence in clinical research, a number of public and private groups have called for a publicly accessible, comprehensive, and transparent registry of relevant information on clinical trials for drugs and biologics. The public and various entities within the medical community (health care providers, researchers, medical journal editors, pharmaceutical companies, health insurers, and regulators) have different expectations and perceived needs regarding a public clinical trial registry. The IOM Committee on Clinical Trial Registries hosted a workshop on June 27, 2005, to obtain much-needed input from members of the public, public advocate groups, and the broader community of journal editors, pharmaceutical and biotech leaders, NIH, and the FDA. Participants discussed the data elements that have been at the core of debate and commented on issues of compliance and implementation of a national clinical trial registry. Developing a National Registry of Pharmacologic and Biologic Clinical Trials: Workshop Report inlcudes discussions at the workshop centered on the following five concepts, and are described within this report: 1) Purpose, 2) Which Trials to Include, 3) Delayed Disclosure Mechanism, 4) Reporting Results of Completed Trials, and 5) Compliance.

Principles, Methods, and Applications for Clinical Research

Principles of Good Clinical Practice

World Medical Association Declaration of Helsinki

Ethical Considerations When Preparing a Clinical Research Protocol

Functional MRI

Ethical and Legal Issues of Including Women in Clinical Studies, Volume 1

Written by experts with extensive clinical and scientific experience, this comprehensive textbook presents the state of the art in auditory evoked potentials. Opening chapters explain the nature of electrical fields that generate surface recorded potentials, summarize the imaging modalities that complement evoked potential studies, and review acoustics and instrumentation. Major sections examine the anatomy and physiology of the auditory periphery, brainstem, and cortex and the principles and clinical applications of auditory, myogenic, visual, somatosensory, and vestibular evoked potentials. Chapters present hands-on laboratory exercises and clinical case studies. A full-color insert includes 3D images from multi-channel evoked potentials and functional imaging.

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.

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.

This revised second edition covers the pharmacologic principles underlying the individualization of patient therapy and contemporary drug development, focusing on the fundamentals that underlie the clinical use and contemporary development of pharmaceuticals. Authors drawn from academia, the pharmaceutical industry and government agencies cover the spectrum of material, including pharmacokinetic practice questions, covered by the basic science section of the certifying examination offered by the American Board of Clinical Pharmacology. This unique reference is recommended by the Board as a study text and includes modules on drug discovery and development to assist students as well as practicing pharmacologists. Unique breadth of coverage ranging from drug discovery and development to individualization and quality assessment of drug therapy Unusual cohesive of presentation that stems from author participation in an ongoing popular NIH course Instructive linkage of pharmacokinetic theory and applications with provision of sample problems for self-study Wide-ranging perspective of authors drawn from the ranks of Federal agencies, academia and the pharmaceutical industry Expanded coverage of pharmacogenetics Expanded coverage of drug transporters and their role in interactions Inclusion of new material on enzyme induction mechanisms in chapters on drug metabolism and drug interactions A new chapter on drug discovery that focuses on oncologic agents Inclusion of therapeutic antibodies in chapter on biotechnology products

Atkinson's Principles of Clinical Pharmacology

From Bench to Bedside

Sharing Clinical Trial Data

Basic Principles of Clinical Research and Methodology

Principles of Clinical Pharmacology

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

Using clinical examples and citing liberally from the peer-reviewed literature, this book shows how statistical priniciples can improve medical decisions.

Basic Science Methods for Clinical Researchers addresses the specific challenges faced by clinicians without a conventional science background. The aim of the book is to introduce the reader to core experimental methods commonly used to answer questions in basic science research and to outline their relative strengths and limitations in generating conclusive data. This book will be a vital companion for clinicians undertaking laboratory-based science. It will support clinicians in the pursuit of their academic interests and in making an original contribution to their chosen field. In doing so, it will facilitate the development of tomorrow's clinician scientists and future leaders in discovery science. Serves as a helpful guide for clinical researchers who lack a conventional science background Organized around research themes pertaining to key biological molecules, from genes, to proteins, cells, and model organisms Features protocols, techniques for troubleshooting common problems, and an explanation of the advantages and limitations of a technique in generating conclusive data Appendices provide resources for practical research methodology, including legal frameworks for using stem cells and animals in the laboratory, ethical considerations, and good laboratory practice (GLP)

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

Basic Principles and Clinical Practice

Basic Principles and Clinical Significance of Oxidative Stress

Drug Discovery and Clinical Research

Auditory Evoked Potentials

ethical principles and guidelines for the protection of human subjects of research

Principles of Research Design and Drug Literature Evaluation

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.

Sleep-related abnormalities occurring as a result of allergic disorders can impact an affected individual's health and overall well-being in a myriad of ways. This comprehensive book thoroughly covers the management of allergic and sleep disorders, providing a detailed discussion on how these co-occurring, often overlapping conditions can be treated in a personalized and patient-oriented manner. Allergy and Sleep: Basic Principles and Clinical Practice takes care to include a wide range of multidisciplinary perspectives required to effectively assess and manage allergy and sleep disorders, from allergists, sleep medicine specialists, otolaryngologists, and dermatologists, to primary care physicians, pharmacists, psychologists, and other researchers. Allergy and Sleep begins with a thorough grounding on the science of sleep, allergy, immunology, circadian rhythms and circadian immunology. Part II addresses assessment and treatment of common allergic diseases with comorbid sleep components, in a practical, easy-to-use case-based format. Later sections closely examine sleep-related disturbances commonly associated with asthma, allergic rhinitis, and atopic disease; providing treatment guidelines, and detail various approaches to management throughout the patient's lifespan. This resource concludes with a review of disease, sleep and circadian-specific therapeutics. Written by experts in their respective fields, Allergy and Sleep: Basic Principles and Clinical Practice is an ideal resource and important reference for any clinician working with patients suffering from sleep-related abnormalities due to allergic disorders.

Concepts and Principles for Advanced Practice Nurses

Statistical Design, Monitoring, and Analysis of Clinical Trials

Clinical Research

Principles and Practice of Clinical Research