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Atkinson's Principles of Clinical Pharmacology - Shiew-Mei Huang 2021-10-16
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

Clinical and Translational Science - David Robertson 2016-11-25
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 edition has been prepared with 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 human research. The book moves 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 Addresses drug discovery, drug repurposing and development, innovative and improved approaches to go/no-go decisions in drug development, and traditional and innovative clinical trial designs

Beyond the HIPAA Privacy Rule - Institute of Medicine 2009-03-24

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.

Conflict of Interest in Medical Research, Education, and Practice - Institute of Medicine 2009-09-16

Collaborations of physicians and researchers with industry can provide valuable benefits to society, particularly in the translation of basic scientific discoveries to new therapies and products. Recent reports and news stories have, however, documented disturbing examples of relationships and practices that put at risk the integrity of medical research, the objectivity of professional education, the quality of patient care, the soundness of clinical practice guidelines, and the public's trust in medicine. Conflict of Interest in Medical Research, Education, and Practice provides a comprehensive look at conflict of interest in medicine. It offers principles to inform the design of policies to identify, limit, and manage conflicts of interest without damaging constructive collaboration with industry. It calls for both short-term actions and long-term commitments by institutions and individuals, including leaders of academic medical centers, professional societies, patient advocacy groups, government agencies, and drug, device, and pharmaceutical companies. Failure of the medical community to take convincing action on conflicts of interest invites additional legislative or regulatory measures that may be overly broad or unduly burdensome. Conflict of Interest in Medical Research, Education, and Practice makes several recommendations for strengthening conflict of interest policies and curbing relationships that create risks with little benefit. The book will serve as an invaluable resource for individuals and organizations committed to high ethical standards in all realms of medicine.

Introduction to Research and Medical Literature for Health Professionals - J. Glenn Forister 2019-03-12

Introduction to Research and Medical Literature for Health Professionals, Fifth Edition is an essential resource to help students, faculty, and practitioners understand the research process, interpret data, comprehend results, and incorporate findings into practice. From choosing a research project and developing the research process design, to systematically gathering information, analyzing, interpreting data, differentiating among conflicting results, and finally understanding the overall evaluation, Introduction to Research and Medical Literature for Health Professionals, Fifth Edition will ease fears and help students and practitioners develop research skills to acquire and contribute knowledge that benefits their patients.

Research in Medical and Biological Sciences - Petter Laake 2015-06-05

Research in Medical and Biological Sciences covers the wide range of topics that a researcher must be familiar with in order to become a successful biomedical scientist. Perfect for aspiring as well as practicing professionals in the medical and biological sciences, this publication discusses a broad range of topics that are common yet not traditionally considered part of formal curricula, including philosophy of science, ethics, statistics, and grant applications. The information presented in this book also facilitates communication across conventional disciplinary boundaries, in line with the increasingly multidisciplinary nature of modern research projects. Covers the breadth of topics that a researcher must understand in order to be a successful experimental scientist Provides a broad scientific perspective that is perfect for students with various professional backgrounds Contains easily accessible, concise

material about diverse methods Includes extensive online resources such as further reading suggestions, data files, statistical tables, and the StaTable application package Emphasizes the ethics and statistics of medical and biological sciences

Finding What Works in Health Care - Institute of Medicine 2011-07-20

Healthcare decision makers in search of reliable information that compares health interventions increasingly turn to systematic reviews for the best summary of the evidence. Systematic reviews identify, select, assess, and synthesize the findings of similar but separate studies, and can help clarify what is known and not known about the potential benefits and harms of drugs, devices, and other healthcare services. Systematic reviews can be helpful for clinicians who want to integrate research findings into their daily practices, for patients to make well-informed choices about their own care, for professional medical societies and other organizations that develop clinical practice guidelines. Too often systematic reviews are of uncertain or poor quality. There are no universally accepted standards for developing systematic reviews leading to variability in how conflicts of interest and biases are handled, how evidence is appraised, and the overall scientific rigor of the process. In Finding What Works in Health Care the Institute of Medicine (IOM) recommends 21 standards for developing high-quality systematic reviews of comparative effectiveness research. The standards address the entire systematic review process from the initial steps of formulating the topic and building the review team to producing a detailed final report that synthesizes what the evidence shows and where knowledge gaps remain. Finding What Works in Health Care also proposes a framework for improving the quality of the science underpinning systematic reviews. This book will serve as a vital resource for both sponsors and producers of systematic reviews of comparative effectiveness research.

The Design and Development of Novel Drugs and Vaccines - Tarun Kumar Bhatt 2021-01-21

The Design and Development of Novel Drugs and Vaccines: Principles and Protocols presents both in silico methods and experimental protocols for vaccine and drug design and development, critically reviewing the most current research and emphasizing approaches and technologies that accelerate and lower the cost of product development. Sections review the technologies and approaches used to identify, characterize and establish a protein as a new drug and vaccine target, cover several molecular methods for in vitro studies of the desired target, and present various physiological parameters for in vivo studies. The book includes preclinical trials and research, along with information on FDA approval. Covers both in silico methods and experimental protocols for vaccine and drug development in a single, accessible volume Offers a holistic accounting of how developments in bioinformatics and large experimental datasets can be used in the development of vaccines and drugs Shows researchers the entire gamut of current therapies, ranging from computational inputs to animal studies Reviews the most current, cutting-edge research available on vaccine and drug design and development

Principles and Practice of Clinical Research - John I. Gallin 2011-04-28

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

Principles and Practice of Clinical Research - John I. Gallin 2012-05-31

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 patient-based research protocols that comply with rigorous study design, ethical, and regulatory requirements.

Women and Health Research - Institute of Medicine 1994-02-01

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 womenâ€"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: Scientificâ€"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 Ethicalâ€"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. Legalâ€"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. Riskâ€"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.

Statistical Design, Monitoring, and Analysis of Clinical Trials - Weichung Joe Shih 2021-10-26

Statistical Design, Monitoring, and Analysis of Clinical Trials, Second Edition concentrates on the biostatistics component of clinical trials. This new edition is updated throughout and includes five new chapters. Developed from the authors’ courses taught to public health and medical students, residents, and fellows during the past 20 years, the text shows how biostatistics in clinical trials is an integration of many fundamental scientific principles and statistical methods. The book begins with ethical and safety principles, core trial design concepts, the principles and methods of sample size and power calculation, and analysis of covariance and stratified analysis. It then focuses on sequential designs and methods for two-stage Phase II cancer trials to Phase III group sequential trials, covering monitoring safety, futility, and efficacy. The authors also discuss the development of sample size reestimation and adaptive group sequential procedures, phase 2/3 seamless design and

trials with predictive biomarkers, exploit multiple testing procedures, and explain the concept of estimand, intercurrent events, and different missing data processes, and describe how to analyze incomplete data by proper multiple imputations. This text reflects the academic research, commercial development, and public health aspects of clinical trials. It gives students and practitioners a multidisciplinary understanding of the concepts and techniques involved in designing, monitoring, and analyzing various types of trials. The book's balanced set of homework assignments and in-class exercises are appropriate for students and researchers in (bio)statistics, epidemiology, medicine, pharmacy, and public health.

Principles and Practice of Clinical Trials - Steven Piantadosi 2022-09-21

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.

The Principles and Practice of Narrative Medicine - Rita Charon 2017

The Principles and Practice of Narrative Medicine articulates the ideas, methods, and practices of narrative medicine. Written by the originators of the field, this book provides the authoritative starting place for any clinicians or scholars committed to learning of and eventually teaching or practicing narrative medicine.

Principles of Research Methodology - Phyllis G. Supino 2012-06-22

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.

Advances in Protein Molecular and Structural Biology Methods - Timir Tripathi 2022-01-14

Advances in Protein Molecular and Structural Biology Methods offers a complete overview of the latest tools and methods applicable to the study of proteins at the molecular and structural level. The book begins with sections exploring tools to optimize recombinant protein expression and biophysical techniques such as fluorescence spectroscopy, NMR, mass spectrometry, cryo-electron microscopy, and X-ray crystallography. It then moves towards computational approaches, considering structural bioinformatics, molecular dynamics simulations, and deep machine learning technologies. The book also covers methods applied to intrinsically disordered proteins (IDPs)followed by chapters on protein interaction networks, protein function, and protein design and engineering. It provides researchers with an extensive toolkit of methods and techniques to draw from when conducting their own experimental work, taking them from foundational concepts to practical application. Presents a thorough overview of the latest and emerging methods and technologies for protein study Explores biophysical techniques, including nuclear magnetic resonance, X-ray crystallography, and cryo-electron microscopy Includes computational and machine learning methods Features a section dedicated to tools and techniques specific to studying intrinsically disordered proteins

Principles of Cancer Treatment and Anticancer Drug Development - Wolfgang Link 2019-09-10

This book explains how current medicines against cancer work and how we find new ones. It provides an easy-to-understand overview of current options to treat patients with cancer, which includes Surgery, Radiation therapy, Chemotherapy, Targeted therapy and Immunotherapy. The efficiency of all these treatments is limited by the capacity of cancer cells to escape therapy. This book explains the mechanisms of anti-cancer drug resistance and strategies to overcome it. The discovery and development process of a new drug is detailed beginning with the identification and validation of a therapeutic target, the identification of an inhibitor of the target and its subsequent preclinical and clinical development until its approval by regulatory authorities. Particular emphasis has been given to specific aspects of the development process including lead generation and optimization, pharmacokinetics, ADME analysis, pharmacodynamics, toxicity and efficacy assessment, investigational new drug (IND) and new drug application (NDA) and the design of clinical trial and their phases. The book covers many aspects of modern personalized oncology and discusses economic aspects of our current system of developing new medicines and its impact on our societies and on future drug research. The author of this book, Dr. Link counts with more than 20 years of experience in biomedical research reflected in numerous publications, patents and key note and plenary presentations at international conferences. Interested readers, students and teachers should read this book as it provides a unique way to learn/teach about basic concepts in oncology and anti-cancer drug research.

Principles of Research Design and Drug Literature Evaluation - Rajender R. Aparasu 2015

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 LinksFrom the 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 primary 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 Ried, PhD, FAPhAEditor-in-Chief Emeritus, Journal of the American Pharmacists AssociationProfessor and Associate Dean for Academic Affairs, College of Pharmacy, University of Texas at Tyler, Tyler, Texas

The Organic Chemistry of Drug Design and Drug Action - Richard B. Silverman 2012-12-02

Standard medicinal chemistry courses and texts are organized by classes of drugs with an emphasis on descriptions of their biological and pharmacological effects. This book represents a new approach based on physical organic chemical principles and reaction mechanisms that allow the reader to extrapolate to many related classes of drug molecules. The Second Edition reflects the significant changes in the drug industry over the past decade, and includes chapter problems and other elements that make the book more useful for course instruction. New edition includes new chapter problems and exercises to help students learn, plus extensive references and illustrations Clearly presents an organic chemist's perspective of how drugs are designed and function, incorporating the extensive changes in the drug industry over the past ten years Well-respected author has published over 200 articles, earned 21 patents, and invented a drug that is under consideration for commercialization

Registries for Evaluating Patient Outcomes - Agency for Healthcare Research and Quality/AHRQ 2014-04-01

This User’s Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure. The User’s Guide was created by researchers affiliated with AHRQ’s Effective Health Care Program, particularly those who participated in AHRQ’s DEcIDE (Developing Evidence to Inform Decisions About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews.

Principles of Research Design and Drug Literature Evaluation -

Rajender R. Aparasu 2014-03-07

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 From the 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 primary 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 Ried, 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

Basic Principles of Drug Discovery and Development - Benjamin E. Blass 2021-03-30

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

Integrating Clinical Research into Epidemic Response - National Academies of Sciences, Engineering, and Medicine 2017-07-26

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.

Don't Make Me Think - Steve Krug 2009-08-05

Five years and more than 100,000 copies after it was first published, it's hard to imagine anyone working in Web design who hasn't read Steve Krug's "instant classic" on Web usability, but people are still discovering it every day. In this second edition, Steve adds three new chapters in the same style as the original: wry and entertaining, yet loaded with insights and practical advice for novice and veteran alike. Don't be surprised if it completely changes the way you think about Web design. Three New Chapters! Usability as common courtesy -- Why people really leave Web sites Web Accessibility, CSS, and you -- Making sites usable and accessible Help! My boss wants me to _____. -- Surviving executive design whims "I thought usability was the enemy of design until I read the first edition of this book. Don't Make Me Think! showed me how to put myself in the position of the person who uses my site. After reading it over a couple of hours and putting its ideas to work for the past five years, I can say it has done more to improve my abilities as a Web designer than any other book. In this second edition, Steve Krug adds essential ammunition for those whose bosses, clients, stakeholders, and marketing managers insist on doing the wrong thing. If you design, write, program, own, or manage Web sites, you must read this book." -- Jeffrey Zeldman, author of Designing with Web Standards

Methods of Behavior Analysis in Neuroscience - Jerry J. Buccafusco 2000-08-29

Using the most well-studied behavioral analyses of animal subjects to promote a better understanding of the effects of disease and the effects of new therapeutic treatments on human cognition, Methods of Behavior Analysis in Neuroscience provides a reference manual for molecular and cellular research scientists in both academia and the pharmaceutic

Principles of Clinical Research - Institute of Clinical Research 2001

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.

Handbook of Research Methodology - 9781545703403

This comprehensive Handbook is aimed at both academic researchers and practitioners in the field of research. The book's 8 chapters, provide in-depth coverage of research methods based on the revised syllabus of various universities especially considering the students of under graduate, post graduate and doctorate level. This book is a product of extensive literature survey made by the authors. The authors have made sincere efforts to write the book in simple language. The book comprises all the aspects according to new syllabus of PCI and APJ Abdul Kalam Technical University, Lucknow. Though this book is intended for the use

of pharmacy students of any level yet it can also be useful to students of applied fields and medical students. The book deals with interdisciplinary fields such as finding research problems, writing research proposals, obtaining funds for research, selecting research designs, searching the literature and review, collection of data and analysis, preparation of thesis, writing research papers for journals, citation and listing of references, preparation of visual materials, oral and poster presentation in conferences, minutes of meetings, and ethical issues in research. At the end of every chapter and book some questions related to chapter have been mentioned for the support of students to understand the subject. Valuable suggestions for the improvement of this book are most welcome.

Sharing Clinical Trial Data - Institute of Medicine 2015-04-20

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.

Pharmacy Practice and The Law - Richard Abood 2011

The Sixth Edition of this best-selling text includes updates to account for new legal, regulatory and policy developments. Pharmacy Practice and the Law, Sixth Edition provides background, history and discussion of the law so as to enable the student to not only learn the facts, but to help them understand, apply and critically evaluate the information. The issues covered in this text are discussed in non-legal, easy to understand language. Challenging open-ended discussion questions and edited cases are included in every chapter to facilitate discussion and critical thinking. Citations to all laws, court cases, regulations and other documents are provided. An online instructor’s manual is available. Pharmacy Practice and the Law, Sixth Edition, is a useful resource both for teaching the facts of pharmacy law and for stimulating critical thinking issues in pharmacy law.

Drug Design: Principles and Applications - Abhinav Grover 2017-08-09

This book offers an in-depth discussion of the latest strategies in the field of drug design and their applications in various disorders, in order to encourage readers to undertake their own projects.It also includes the contemporary application of drug-designing methodologies to inspire others to further expand the utility of this field in other diseases.It is intended for advanced undergraduate and graduate students, postdocs, researchers, lecturers and professors in bioinformatics, computational biology, medicine, pharmaceutics and other related fields.

Essentials of Research Design and Methodology - Geoffrey R. Marczyk 2010-06-03

Master the essential skills for designing and conducting a successful research project Essentials of Research Design and Methodology contains practical information on how to design and conduct scientific

research in the behavioral and social sciences. This accessible guide covers basic to advanced concepts in a clear, concrete, and readable style. The text offers students and practitioners in the behavioral sciences and related disciplines important insights into identifying research topics, variables, and methodological approaches. Data collection and assessment strategies, interpretation methods, and important ethical considerations also receive significant coverage in this user-friendly guide. Essentials of Research Design and Methodology is the only available resource to condense the wide-ranging topics of the field into a concise, accessible format for handy and quick reference. As part of the Essentials of Behavioral Science series, this book offers a thorough review of the most relevant topics in research design and methodology. Each concise chapter features numerous callout boxes highlighting key concepts, bulleted points, and extensive illustrative material, as well as "Test Yourself" questions that help you gauge and reinforce your grasp of the information covered.

Pharmaceutical Quality by Design - Sarwar Beg 2019-03-27

Pharmaceutical Quality by Design: Principles and Applications discusses the Quality by Design (QbD) concept implemented by regulatory agencies to ensure the development of a consistent and high-quality pharmaceutical product that safely provides the maximum therapeutic benefit to patients. The book walks readers through the QbD framework by covering the fundamental principles of QbD, the current regulatory requirements, and the applications of QbD at various stages of pharmaceutical product development, including drug substance and excipient development, analytical development, formulation development, dissolution testing, manufacturing, stability studies, bioequivalence testing, risk and assessment, and clinical trials. Contributions from global leaders in QbD provide specific insight in its application in a diversity of pharmaceutical products, including nanopharmaceuticals, biopharmaceuticals, and vaccines. The inclusion of illustrations, practical examples, and case studies makes this book a useful reference guide to pharmaceutical scientists and researchers who are engaged in the formulation of various delivery systems and the analysis of pharmaceutical product development and drug manufacturing process. Discusses vital QbD precepts and fundamental aspects of QbD implementation in the pharma, biopharma and biotechnology industries Provides helpful illustrations, practical examples and research case studies to explain QbD concepts to readers Includes contributions from global leaders and experts from academia, industry and regulatory agencies

Drug Information - Patrick M. Malone 2010-05-12

Extensive coverage of the Internet as a source of and distribution means for drug information, and detailed sections on evaluating medical literature from clinical trials Audience includes Pharmacists, Pharmacy students and Pharmacy schools Updated to include using PDAs for medication information Covers the ethical and legal aspects of drug information management Nothing else like it on the market

Drug Delivery - W. Mark Saltzman 2001-03-15

Synthetic materials are a tremendous potential resource for treating human disease. For the rational design of many of these biomaterials it is necessary to have an understanding of polymer chemistry and polymer physics. Equally important to those two fields is a quantitative understanding of the principles that govern rates of drug transport, reaction, and disappearance in physiological and pathological situations. This book is a synthesis of these principles, providing a working foundation for those in the field of drug delivery. It covers advanced drug delivery and contemporary biomaterials.

Principles of Translational Science in Medicine - Martin Wehling 2021-07-15

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 such 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 Essential Guide to Pharmacy Residency Research - Yardlee Kauffman 2020-09-25

The Essential Guide to Pharmacy Residency Research provides pharmacy students, residents, and practitioners with an accessible and practical overview of how to complete a high-quality research project. Each step in the research process is explained using a practical approach, with helpful tips and key takeaways to consider through each phase of the project. Topics covered in this book include developing a research question, selecting a study design, submitting an Institutional Review Board protocol, designing data collection tools, identifying appropriate statistical tests, and interpreting biostatistics.

Social Science Research - Anol Bhattacherjee 2012-04-01

This book is designed to introduce doctoral and graduate students to the process of conducting scientific research in the social sciences, business, education, public health, and related disciplines. It is a one-stop, comprehensive, and compact source for foundational concepts in behavioral research, and can serve as a stand-alone text or as a supplement to research readings in any doctoral seminar or research methods class. This book is currently used as a research text at universities on six continents and will shortly be available in nine different languages.

Pharmacoepidemiology - Brenda Waning 2001

The not-to-be-missed, benchmark volume on the growing area of stud in the PharmD pharmacy curriculum. Provides a foundation for assessing the nature and extent of drug-taking behaviors. Text is adapted from the author's self-paced learning modules, developed for the Massachusetts College of Pharmacy.

Research Methods for Pharmaceutical Practice and Policy - Rajender R. Aparasu 2011

This text provides the theory and practice for conducting pharmaceutical policy research. It covers all aspects of scientific research from conceptualising to statistical analysis. It also provides scientific basis and a good understanding of the principles and practice of conducting pharmaceutical policy research.

Encyclopedia of Research Design - Neil J. Salkind 2010-06-22

"Comprising more than 500 entries, the Encyclopedia of Research Design explains how to make decisions about research design, undertake research projects in an ethical manner, interpret and draw valid inferences from data, and evaluate experiment design strategies and results. Two additional features carry this encyclopedia far above other works in the field: bibliographic entries devoted to significant articles in the history of research design and reviews of contemporary tools, such as software and statistical procedures, used to analyze results. It covers the spectrum of research design strategies, from material presented in introductory classes to topics necessary in graduate research; it addresses cross- and multidisciplinary research needs, with many examples drawn from the social and behavioral sciences, neurosciences, and biomedical and life sciences; it provides summaries of advantages and disadvantages of often-used strategies; and it uses hundreds of sample tables, figures, and equations based on real-life cases."--Publisher's description.