Publishing And Presenting Clinical Research

Presenting Your ResearchCore Resources for Clinical ResearchThe Management of Clinical TrialsPublishing and Presenting Clinical ResearchSmall Clinical TrialsThe Lancet Handbook of Essential Concepts in Clinical ResearchResearch Methods for Massage and Holistic Therapies - E-BookDesigning Clinical ResearchEssentials of Writing Biomedical Research Papers. Second EditionMedical Research for HireThe CRA's Guide to Monitoring Clinical ResearchHow to Read a PaperPrinciples and Practice of Clinical ResearchClinical Trials in Vulnerable PopulationsClinical Trials HandbookPublishing and Presenting Clinical ResearchFundamentals of Clinical TrialsTextbook of Clinical Trials in OncologyHow to Write, Publish, and Present in the Health SciencesThe Comprehensive Guide To Clinical ResearchPublishing Your Medical ResearchPublishing Addiction ScienceRehabilitation Research - E-BookMultidisciplinary Guidebook for Clinical Geriatric ResearchHandbook for Clinical ResearchSharing Clinical Trial DataSample Size Calculations in Clinical ResearchEthical Issues in Clinical ResearchEssential Concepts in Clinical ResearchEssentials of Clinical ResearchDesign and Analysis of Clinical TrialsClinical TrialsIntegrating Clinical Research into Epidemic ResponseTextbook of Clinical TrialsClinical Research and the LawSingle-Case Experimental Designs for Clinical Research and Neurorehabilitation SettingsTranslational and Experimental Clinical ResearchClinical Research TransformedClinical Research Made EasyClinical Trials

Presenting Your Research

A unique, unifying treatment for statistics and science in clinical trials What sets this volume apart from the many books dealing with clinical trials is its integration of statistical and clinical disciplines. Stressing communication between biostatisticians and clinical scientists, this work clearly relates statistical interpretation to clinical issues arising in different stages of pharmaceutical research and development. Plus, the principles presented here are universal enough to be easily adapted in non-biopharmaceutical settings. Design and Analysis of Clinical Trials tackles concepts and methodologies. It not only covers statistical basics such as uncertainty and bias, design considerations such as patient selection, randomization, and the different types of clinical trials but also deals with various methods of data analysis, group sequential procedures for interim analysis, efficacy data evaluation, analysis of safety data, and more. Throughout, the book: * Surveys current and emerging clinical issues and newly developed statistical methods * Presents a critical review of statistical methodologies in various therapeutic areas * Features case studies from actual clinical trials * Minimizes the mathematics involved, making the material widely accessible * Offers each chapter as a self-contained entity * Includes illustrations to highlight the text This monumental reference on all facets of clinical trials is important reading for physicians, clinical and medical researchers, pharmaceutical scientists, clinical programmers, biostatisticians, and anyone involved in this burgeoning area of clinical research. It can also be used as a textbook in graduate-level courses in the field.

Core Resources for Clinical Research

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

The Management of Clinical Trials

Publishing and Presenting Clinical Research

This new edition provides clinicians and trainees with guidance on the latest clinical research techniques and publishing in medical literature. Divided into six sections, the book begins with an overview of research and evidence-based medicine, then discusses the strengths and limitations of specific research designs including randomised controlled trials, cohort studies, case control studies and much more. The following sections cover reporting guidelines, writing a good research paper, sample size calculations, subgroup analyses and associated topics such as research ethics and patient consent. The second edition has been fully revised and expanded and includes new advanced content. Clinical images and figures further enhance the comprehensive text. Key points New edition providing guidance on latest clinical research techniques and publishing in medical literature Fully revised and expanded content with new advanced topics Internationally recognised author team Previous edition (9788184488906) published in 2010

Small Clinical Trials

In this Information Age, the practices of clinical medicine should no longer be based on what clinical doctors actively know. Rather, all of the importantly practice-relevant knowledge should not only already exist but also be codified in cyberspace, in directly practice-guiding 'expert systems' -- for the benefit of both doctors and patients everywhere. Each of these systems (discipline-specific) would, prompted by a particular type of case presentation, present the doctor a questionnaire specific to cases of the type at issue, and document the doctor's answers to the questions. If at issue would be a case of complaint about a (particular type of) sickness, the system would translate the resulting diagnostic profile of the case into the corresponding probabilities of the illnesses to be considered. Similarly, if at issue would be an already-diagnosed case of a particular illness, the system would ask about, and record, the relevant elements in the prognostic profile of the case and then translate this profile into the probabilities of various outcomes to be considered, probabilities specific to the choice of treatment and prospective time in addition to that profile. And besides, these systems would analogously address the causal origin -- etiogenesis -- of cases of particular types of illness. While the requisite knowledge-base for these systems -- notably for the probabilities in them -- has not been addressed by such 'patient-oriented' clinical research as has been conducted (very extensively) up to now, this book delineates the nature of the suitably-transformed research (gnostic). The critically-transformative innovation in the research is the studies' focus on Gnostic Probability Functions -- dia-, etio-, and prognostic -- in the framework of logistic regression models. This book also presents a vision of how this critically-transformative research would most expeditiously be provided for and also conducted, among select sets of academic teaching hospitals.

The Lancet Handbook of Essential Concepts in Clinical Research

This book is an excellent practical primer for researchers who wish to learn how to organize, present, and publish the results of their research. Written in a crystal-clear style with numerous examples, tables, and figures, the book shows how to produce a successful abstract, poster and/or manuscript for publication. This updated edition reflects the growing use of software in preparing and submitting presentations and publications. The posters and oral presentations chapters have been completely rewritten to cover PowerPoint technology. Emphasis is placed on learning how to create graphics for written research. This edition also includes new clinical examples.

Research Methods for Massage and Holistic Therapies - E-Book

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.

Designing Clinical Research

A systematic approach to all aspects of designing andconducting clinical trials The success or failure of clinical trials hinges on hundreds ofdetails that need to be developed, often under less than idealconditions. Written by one of the world's leading trialists,Clinical Trials Handbook: Design and Conduct providesclinicians with a complete guide to designing, conducting, andevaluating clinical trials—teaching them how to simplify theprocess and avoid costly mistakes. The author draws on his extensive clinical trials experience tooutline all steps employed in setting up and running clinicaltrials, from budgeting and fundraising to publishing the results.Along the way, practical advice is offered while also addressing amix of logistical, ethical, psychological, behavioral, andadministrative issues inherent to clinical trials. Topics ofcoverage include: Protocols for drug masking, controls, and treatmentrandomization Consent, enrollment, eligibility, and follow-up procedures Different types of sample size design and data collection andprocessing Working with study centers, research staff, and variouscommittees Monitoring treatment effects and performance, and ensuringquality control Data analysis and access policies for study data anddocuments Clinical Trials Handbook is invaluable for practicingclinicians and trialists who would like to learn more about orimprove their understanding of the design and execution of clinicaltrials. The book is also an excellent supplement for courses onclinical trials at the graduate level.

Essentials of Writing Biomedical Research Papers. Second Edition

Praise for the Second Edition: " this is a useful, comprehensive compendium of almost every possible sample size formula. The strong organization and carefully defined formulae will aid any researcher designing a study." -Biometrics "This impressive book contains formulae for computing sample size in a wide range of settings. One-sample studies and two-sample comparisons for quantitative, binary, and time-to-event outcomes are covered comprehensively, with separate sample size formulae for testing equality, non-inferiority, and equivalence. Many less familiar topics are also covered " – Journal of the Royal Statistical Society Sample Size Calculations in Clinical Research, Third Edition presents statistical procedures for performing sample size calculations during various phases of clinical research and development. A comprehensive and unified presentation of statistical concepts and practical applications, this book includes a well-

balanced summary of current and emerging clinical issues, regulatory requirements, and recently developed statistical methodologies for sample size calculation. Features: Compares the relative merits and disadvantages of statistical methods for sample size calculations Explains how the formulae and procedures for sample size calculations can be used in a variety of clinical research and development stages Presents real-world examples from several therapeutic areas, including cardiovascular medicine, the central nervous system, anti-infective medicine, oncology, and women's health Provides sample size calculations for dose response studies, microarray studies, and Bayesian approaches This new edition is updated throughout, includes many new sections, and five new chapters on emerging topics: two stage seamless adaptive designs, cluster randomized trial design, zero-inflated Poisson distribution, clinical trials with extremely low incidence rates, and clinical trial simulation.

Medical Research for Hire

The CRA's Guide to Monitoring Clinical Research

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

How to Read a Paper

Publishing Your Medical Research is the second edition of the award-winning book that provides practical information on how to write a publishable paper. This edition includes additional details to help medical researchers succeed in the competitive "publish or perish" world. Using a direct and highly informative style, it does more than help you write a paper; it presents the technical information, invaluable modern advice, and practical tips you need to get your paper accepted for publication. A singular source for the beginning and experienced researcher alike, Publishing Your Medical Research is a

must for any physician, fellow, resident, medical scientist, graduate student, or biostatistician seeking to be published.

Principles and Practice of Clinical Research

This book Clinical Trials in Vulnerable Populations has 12 chapters divided into 4 sections: Minority Patients, Women, Medically Compromised Patients and Clinical Trials. Contributing authors came from several countries, from Serbia to Turkey. The book was edited by Professor Milica Prostran MD, Ph.D., specialist in Clinical Pharmacology. The potential reader is shown a modern approach to clinical trials in vulnerable populations, from different points of view. The chapters deal at length and clarity with their topics. Finally, I believe, that this book I edited and reviewed with dedication will capture the attention of many readers, from medical students to practicing doctors and pharmacists. All of whom must consider this very important field of medicine: clinical trials in vulnerable patients.

Clinical Trials in Vulnerable Populations

This practical guide speaks to two audiences: those who read and those who conduct research. Clinicians are medical detectives by training. For each patient, they assemble clinical clues to establish causes of signs and symptoms. The task involves both clinical acumen and knowledge of medical research. This book helps guide clinicians through this detective work, by enabling them to make sense of research and to review medical literature critically. It will also be invaluable to researchers who conduct clinical research, particularly randomized controlled trials. Building on previously published, peer-reviewed articles from The Lancet, this handbook is essential for busy clinicians and active researchers interested in research methods. Written by leaders in the field of clinical research who have published extensively with authorship of hundreds of articles in medical journals. The authorship includes one of the three authors of the CONSORT guidelines for the reporting of randomized controlled trials. The book presents the essential concepts to a wide array of topics including randomized control trials, descriptive studies, cohort studies, case-control studies, bias, and screening tests. The book utilises a readable and humorous prose style, lightening what can be a difficult area for clinical readers. Derived from decades of teaching clinical research in seminar settings the book will empower clinicians to make sense of, and critically appraise, current medical research and will enable researchers to enrich the quality of their work. The updated new edition includes six new chapters: Surrogate endpoints Limitations of observational epidemiology Participant recruitment Practicalities of double-blinding Randomized trials in the context of a prospective meta-analysis Reporting studies in medical journals: CONSORT

Clinical Trials Handbook

Required reading in many medical and healthcare institutions, How to Read a Paper is a clear and wide-ranging introduction to evidence-based medicine and healthcare, helping readers to understand its central principles, critically evaluate published data, and implement the results in practical settings. Author Trisha Greenhalgh guides readers through each fundamental step of inquiry, from searching the literature to assessing methodological quality and appraising statistics. How to Read a Paper addresses the common criticisms of evidence-based healthcare, dispelling many of its myths and misconceptions, while providing a pragmatic framework for testing the validity of healthcare literature. Now in its sixth edition, this informative text includes new and expanded discussions of study bias, political interference in published reports, medical statistics, big data and more. Offers user-friendly guidance on evidence-based healthcare that is applicable to both experienced and novice readers Authored by an internationally recognised practitioner and researcher in evidence-based healthcare and primary care Includes updated references, additional figures, improved checklists and more How to Read a Paper is an ideal resource for healthcare students, practitioners and anyone seeking an accessible introduction to evidence-based healthcare.

Publishing and Presenting Clinical Research

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

Fundamentals of Clinical Trials

Covering the full range of rehabilitation research with a clear, easy-to-understand approach, this resource will help you analyze and apply research to practice. Rehabilitation Research: Principles and Applications examines traditional experimental designs as well as nonexperimental and emerging approaches, including qualitative research, single-system design, outcomes research, and survey research. Clinical case studies and references will enhance your skills as a scientist-practitioner. Written by noted educators Russell Carter and Jay Lubinsky, this book emphasizes evidence-based practice within physical therapy, occupational therapy, and other rehabilitation professions. Discipline-specific examples are drawn from three major fields: physical therapy, occupational therapy, and speech-language pathology. Unique! Coverage of non-experimental research includes chapters on clinical case reports and qualitative research, so you can understand a wide range of research methods and when it is most appropriate to use each type. Expanded Single-Subject Design chapter

provides a more thorough explanation and examples of multiple baselines, alternating treatments, and interactions -- designs that can be use in everyday clinical practice. Finding Research Literature chapter includes step-by-step descriptions of literature searches within different rehab professions. Student resources on a companion Evolve website allow you to review important concepts with exercises and discussion questions, research article analyses, and a downloadable spreadsheet. Unique! New Evidence-Based Practice chapter provides an overview of the important concepts of EBP and the WHO model of health and disease. Discussion questions on the companion Evolve website provide you with ideas for further study. Unique! Research article analyses on Evolve provide more in-depth analysis and demonstrate the writing style you should employ. New authors Russell Carter and Jay Lubinsky bring an interdisciplinary focus and a stronger emphasis on evidence-based practice.

Textbook of Clinical Trials in Oncology

The legal implications of conducting clinical research and trials are becoming more complex. Everyone involved in clinical research increasingly needs to be aware of not only the ethical issues at stake but also how the law affects medical practice and research. Much of clinical research and trial law and litigation is comparatively recent and researchers need to ensure current compliance on a wide range of issues. Including: standards and duty of care informed consent conflicts of interest research contracts establishing clinical trials the disclosure and withholding of clinical trial results Clinical Research and the Law comprehensively discusses these topics and provides the answers to the legal questions and potential pitfalls encountered in medical research. It is an up-to-date, practical guide for clinical investigators and their institutional administrators, particularly risk managers and research administrators, as well as healthcare administrators and members of institutional review boards. This book is also a key resource for medical students, postgraduate research students, practicing attorneys and counselors for teaching hospitals and institutions undertaking clinical research and contract research organizations.

How to Write, Publish, and Present in the Health Sciences

The Comprehensive Guide To Clinical Research

This classic reference, now updated with the newest applications and results, addresses the fundamentals of such trials based on sound scientific methodology, statistical principles, and years of accumulated experience by the three authors.

Publishing Your Medical Research

There is an increasing need for educational resources for statisticians and investigators. Reflecting this, the goal of this book is to provide readers with a sound foundation in the statistical design, conduct, and analysis of clinical trials. Furthermore, it is intended as a guide for statisticians and investigators with minimal clinical trial experience who are interested in pursuing a career in this area. The advancement in genetic and molecular technologies have revolutionized drug development. In recent years, clinical trials have become increasingly sophisticated as they incorporate genomic studies, and efficient designs (such as basket and umbrella trials) have permeated the field. This book offers the requisite background and expert guidance for the innovative statistical design and analysis of clinical trials in oncology. Key Features: Cutting-edge topics with appropriate technical background Built around case studies which give the work a "hands-on" approach Real examples of flaws in previously reported clinical trials and how to avoid them Access to statistical code on the book’s website Chapters written by internationally recognized statisticians from academia and pharmaceutical companies Carefully edited to ensure consistency in style, level, and approach Topics covered include innovating phase I and II designs, trials in immune-oncology and rare diseases, among many others

Publishing Addiction Science

This comprehensive resource covers a broad array of research strategies available to massage therapists to give them the tools they need to be knowledgeable readers of research literature, as well as active researchers. The primary focus of the book is on the quantitative aspect of research that encompasses the principal types of studies most extensively used in the various health care professions, specifically massage therapy. Extensive coverage is also given to the qualitative and integrative research categories that are progressively gaining recognition among researchers in various health science disciplines and professions. Accommodates the March 2003 mandate from the Commission on Massage Therapy Accreditation (COMTA) that massage therapy schools incorporate into their curricula provisions to ensure a research literate profession. Examples and techniques for interpreting research guide practitioners and students to be knowledgeable readers of massage therapy research, allowing application to practice. Relies heavily on concept maps, flowcharts, tables, and illustrations and excerpts of published studies to augment the book's narrative development of topics by providing pictorial displays and summaries of the material. Literature-based and hypothetical research examples/illustrations from several manual therapy professions employing therapeutic massage make the material pertinent to real-life settings An introductory section at the beginning of each chapter reviews the material covered in the previous chapter and how it relates to the new material. Chapter coverage spans the quantitative, qualitative, and integrative research categories and affiliated research strategies and methods are considered in detail. Review/summary tables give an overview of the narrative development of topics. Boxes provide the essential features of a given topic. Relies on multiple examples of possible research scenarios and illustrative excerpts from the published research literature. Content is cross-referenced for use with the Massage Therapy Foundation's Massage Therapy Research Curriculum Kit to provide both instructors and

students in the 6-, 15-, and 24-hour options/levels an extensively-developed resource in one place. Each chapter includes recommended web sites and software application packages for further information.

Rehabilitation Research - E-Book

This third edition 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 and offers an updated syllabus for conducting a clinical research workshop.

Multidisciplinary Guidebook for Clinical Geriatric Research

This book is a practical resource designed for clinicians, researchers, and advanced students who wish to learn about single-case research designs. It covers the theoretical and methodological underpinnings of single-case designs, as well as their practical application in the clinical and research neurorehabilitation setting. The book briefly traces the history of single-case experimental designs (SCEDs); outlines important considerations in understanding and planning a scientifically rigorous single-case study, including internal and external validity; describes prototypical single-case designs (withdrawal-reversal designs and the medical N-of-1 trial, multiple-baseline designs, alternating-treatments designs, and changing-criterion designs) and required features to meet evidence standards, threats to internal validity, and strategies to address them; addresses data evaluation, covering visual analysis of graphed data, statistical techniques, and clinical significance; and provides a practical ten-step procedure for implementing single-case methods. Each chapter includes detailed illustrative examples from the neurorehabilitation literature. Novel features include: A focus on the neurorehabilitation setting, which is particularly suitable for single-case designs because of the complex and often unique presentation of many patients/clients. A practical approach to the planning, implementation, data analysis, and reporting of single-case designs. An appendix providing a detailed summary of many recently published SCEDs in representative domains in the neurorehabilitation field, covering basic and instrumental activities of daily living, challenging behaviours, disorders of communication and cognition, mood and emotional functions, and motor-sensory disabilities. It is valuable reading for clinicians and researchers in several disciplines working in rehabilitation, including clinical and neuropsychology, education, language and speech pathology, occupational therapy, and physical therapy. It is also an essential resource for advanced students in these fields who need a textbook for specialised courses on research methodology and use of single-case design in applied clinical and research settings.

Handbook for Clinical Research

Now published in its Second Edition, the Textbook of Clinical Trials offers detailed coverage of trial methodology in diverse areas of medicine in a single comprehensive volume. Praise for the First Edition: " very useful as an introduction to clinical research, or for those planning specific studies within therapeutic or disease areas." BRITISH JOURNAL OF SURGERY, Vol. 92, No. 2, February 2005 The book's main concept is to describe the impact of clinical trials on the practice of medicine. It separates the information by therapeutic area because the impact of clinical trials, the problems encountered, and the numbers of trials in existence vary tremendously from specialty to specialty. The sections provide a background to the disease area and general clinical trial methodology before concentrating on particular problems experienced in that area. Specific examples are used throughout to address these issues. The Textbook of Clinical Trials, Second Edition: Highlights the various ways clinical trials have influenced the practice of medicine in many therapeutic areas Describes the challenges posed by those conducting clinical trials over a range of medical specialities and allied fields Additional therapeutic areas are included in this Second Edition to fill gaps in the First Edition as the number and complexity of trials increases in this rapidly developing area Newly covered or updated in the Second Edition: general surgery, plastic surgery, aesthetic surgery, palliative care, primary care, anaesthesia and pain, transfusion, wound healing, maternal and perinatal health, early termination, organ transplants, ophthalmology, epilepsy, infectious disease, neuro-oncology, adrenal, thyroid and urological cancers, as well as a chapter on the Cochrane network An invaluable resource for pharmaceutical companies, the Textbook of Clinical Trials, Second Edition appeals to those working in contract research organizations, medical departments and in the area of public health and health science alike.

Sharing Clinical Trial Data

For many researchers, the need to present relevant and engaging material in the most effective way in an unfamiliar setting presents a potential barrier to their success as professionals. This handy guide tackles the obstacles to effective and successful presentations, considering the range of material which might be presented, the occasions which suit different types of material and the skills needed to present research in a way that is engaging and persuasive. This book addresses questions such as: Why should I give a paper and where might I give a paper? How does the conference system works? How do I prepare an abstract/outline/synopsis? How do I chose my material and prepare it for a conference presentation? How can I prepare effective conference aids? How can I overcome my nerves? How can I prepare and present effective posters for poster presentations? As with the other titles in the Success in Research series, this guide takes a hands-on approach and includes checklists, top tips, exercises and examples to help you remember what you have read and put it immediately to work! The Success in Research series, from Cindy Becker and Pam Denicolo, provides short, authoritative and accessible guides on key areas of professional and research development. Avoiding jargon and cutting to the chase of what you really need to know, these practical and supportive books cover a range of areas from presenting research to achieving impact, and from publishing journal articles to developing proposals. They are essential reading for any student or researcher

interested in developing their skills and broadening their professional and methodological knowledge in an academic context.

Sample Size Calculations in Clinical Research

Every year, hundreds of thousands of healthy volunteers and patients worldwide undertake the journey through the maze that can be clinical trials. Research participants take part in clinical trials for a variety of reasons. The healthy volunteers may be seeking extra money to pay off college tuition, or they may know someone who is suffering and would potentially benefit from the results of the trial. The patient who is terminally ill might participate in a clinical trial simply as a last hope for a cure. Whatever the goals, though, most participants will experience the same sense of bewilderment as they encounter the jargon and medical terminology that they will hear and have to read about and understand during the course of the clinical trial. Clinical Trials: What Patients and Volunteers Need to Know demystifies the entire process, focusing on the process of drug development, and the clinical trial itself. Writing from a lifetime of experience, the author provides important questions to ask those running a clinical trial, key definitions and terms for a participant to know and understand, as well as anecdotes illustrating the clinical trial process. The author also grapples with the idea of "informed consent," providing mechanisms for patients and volunteers to feel fully informed before signing up for the trial. A vital resource for those who are considering enrolling in a clinical trial, or for the parents, friends, or relatives of those involved in a clinical trial, this book takes away the mystery and allows the participant to enter a clinical trial feeling both informed and confident.

Ethical Issues in Clinical Research

This concise book is addressed to researchers, clinical investigators, as well as practicing physicians and surgeons who are interested in the fields of clinical research and trials. It covers some important topics related to clinical trials including an introduction to clinical trials, some aspects concerning clinical trials in pediatric age group, and the unique aspects of the design of clinical trials on stem cell therapy.

Essential Concepts in Clinical Research

Learn rigorous statistical methods to ensure valid clinicaltrials This Second Edition of the critically hailed Clinical Trials buildson the text's reputation as a straightforward and authoritativepresentation of statistical methods for clinical trials. Readersare introduced to the fundamentals of design for various types ofclinical trials and then skillfully guided through the completeprocess of planning the experiment, assembling a study cohort,assessing data, and reporting results. Throughout

the process, theauthor alerts readers to problems that may arise during the courseof the trial and provides commonsense solutions. The author bases the revisions and updates on his own classroomexperience, as well as feedback from students, instructors, andmedical and statistical professionals involved in clinical trials.The Second Edition greatly expands its coverage, ranging fromstatistical principles to controversial topics, includingalternative medicine and ethics. At the same time, it offers morepragmatic advice for issues such as selecting outcomes, samplesize, analysis, reporting, and handling allegations of misconduct.Readers familiar with the First Edition will discover completelynew chapters, including: * Contexts for clinical trials * Statistical perspectives * Translational clinical trials * Dose-finding and dose-ranging designs Each chapter is accompanied by a summary to reinforce the keypoints. Revised discussion questions stimulate critical thinkingand help readers understand how they can apply their newfoundknowledge, and updated references are provided to direct readers tothe most recent literature. This text distinguishes itself with its accessible and broadcoverage of statistical design methods--the crucial building blocksof clinical trials and medical research. Readers learn to conductclinical trials that produce valid qualitative results backed byrigorous statistical methods.

Essentials of Clinical Research

Design and Analysis of Clinical Trials

Today, more than 75 percent of pharmaceutical drug trials in the United States are being conducted in the private sector. Once the sole province of academic researchers, these important studies are now being outsourced to non-academic physicians. According to Jill A. Fisher, this major change in the way medical research is performed is the outcome of two problems in U.S. health care: decreasing revenue for physicians and decreasing access to treatment for patients. As physicians report diminishing income due to restrictive relationships with insurers, increasing malpractice insurance premiums, and inflated overhead costs to operate private practices, they are attracted to pharmaceutical contract research for its lucrative return. Clinical trials also provide limited medical access to individuals who have no or inadequate health insurance because they offer "free" doctors' visits, diagnostic tests, and medications to participants. Focusing on the professional roles of those involved, as well as key research practices, Fisher assesses the risks and advantages for physicians and patients alike when pharmaceutical drug studies are used as an alternative to standard medical care. A volume in the Critical Issues in Health and Medicine series, edited by Rima D. Apple and Janet Golden

Clinical Trials

Provides immediate help for anyone preparing a biomedical paper by givin specific advice on organizing the components of

the paper, effective writing techniques, writing an effective results sections, documentation issues, sentence structure and much more. The new edition includes new examples from the current literature including many involving molecular biology, expanded exercises at the end of the book, revised explanations on linking key terms, transition clauses, uses of subheads, and emphases. If you plan to do any medical writing, read this book first and get an immediate advantage.

Integrating Clinical Research into Epidemic Response

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

Textbook of Clinical Trials

In its extensively revised and updated Second Edition, this book provides a solid foundation for readers interested in clinical research. Discussion encompasses genetic, pharmacoepidemiologic and implementation research. All chapters have been updated with new information and many new tables have been added to elucidate key points. The book now offers discussion on how to handle missing data when analyzing results, and coverage of Adaptive Designs and Effectiveness Designs and new sections on Comparative Effectiveness Research and Pragmatic Trials. Chapter 6 includes new material on Phase 0 Trials, expanded coverage of Futility Trials, a discussion of Medical Device approval, Off Label Drug use and the role of the FDA in regulating advertising. Additional new information includes the role of pill color and shape in association with the placebo effect and an examination of issues surrounding minority recruitment. The final chapter offers a new section on manuscript preparation along with a discussion of various guidelines being adopted by journals: CONSORT, STROBE, PRISMA, MOOSE and others; and coverage of Conflicts of Interest, Authorship, Coercive Citation, and Disclosures in Industry-Related Associations. Building on the strengths of its predecessor in its comprehensive approach and authoritative advice, the new edition offers more of what has made this book a popular, trusted resource for students and working

researchers alike.

Clinical Research and the Law

This volume is a comprehensive textbook for investigators entering the rapidly growing field of translational and experimental clinical research. The book offers detailed guidelines for designing and conducting a study and analyzing and reporting results and discusses key ethical and regulatory issues. Chapters address specific types of studies such as clinical experiments in small numbers of patients, pharmacokinetics and pharmacodynamics, and gene therapy and pharmacogenomic studies. A major section describes modern techniques of translational clinical research, including gene expression, identifying mutations and polymorphisms, cloning, transcriptional profiling, proteomics, cell and tissue imaging, tissue banking, evaluating substrate metabolism, and in vivo imaging.

Single-Case Experimental Designs for Clinical Research and Neurorehabilitation Settings

The needs of clinicians predominate throughout the text, but these needs overlap with those of researchers especially in chapters covering randomized controlled trials. For readers to assess trials accurately they need to understand relevant guidelines on the conduct of trials that are emerging from methodological research. In presenting these discussions to clinicians these chapters will help researchers who also do randomized trials and provide a methodological background that enhances the quality and quantity of their research productivity.

Translational and Experimental Clinical Research

Publishing and Presenting Clinical Research, Fourth Edition is an excellent primer for investigators who wish to learn how to organize, present, and publish results of their research. Written by an experienced clinical researcher and editor, it uses hundreds of examples, tables and figures to show how to produce successful abstracts, posters, oral presentations, and manuscripts for publication. This book also serves as a companion to the popular text, Designing Clinical Research. This edition contains the latest: • Guidance on getting work accepted in medical journals and at scientific meetings • Examples of the do’s and don’ts of data presentation • Explanations of confusing statistical terminology • Templates to get started and avoid writers’ block • Tips for creating simple graphics and tables • Help for those who are not fluent in English • Suggestions about getting the most from a poster session • Checklists for each section of a manuscript or presentation • Advice about authorship and responding to reviewers’ comments Plus with this edition, there is access to a companion website with fully searchable text so you can access the content anytime, anywhere.

Clinical Research Transformed

Clinical trials are used to elucidate the most appropriate preventive, diagnostic, or treatment options for individuals with a given medical condition. Perhaps the most essential feature of a clinical trial is that it aims to use results based on a limited sample of research participants to see if the intervention is safe and effective or if it is comparable to a comparison treatment. Sample size is a crucial component of any clinical trial. A trial with a small number of research participants is more prone to variability and carries a considerable risk of failing to demonstrate the effectiveness of a given intervention when one really is present. This may occur in phase I (safety and pharmacologic profiles), II (pilot efficacy evaluation), and III (extensive assessment of safety and efficacy) trials. Although phase I and II studies may have smaller sample sizes, they usually have adequate statistical power, which is the committee's definition of a "large" trial. Sometimes a trial with eight participants may have adequate statistical power, statistical power being the probability of rejecting the null hypothesis when the hypothesis is false. Small Clinical Trials assesses the current methodologies and the appropriate situations for the conduct of clinical trials with small sample sizes. This report assesses the published literature on various strategies such as (1) meta-analysis to combine disparate information from several studies including Bayesian techniques as in the confidence profile method and (2) other alternatives such as assessing therapeutic results in a single treated population (e.g., astronauts) by sequentially measuring whether the intervention is falling above or below a preestablished probability outcome range and meeting predesigned specifications as opposed to incremental improvement.

Clinical Research Made Easy

Publishing Addiction Science is a comprehensive guide for addiction scientists facing the complex process of contributing to scholarly journals. Written by an international group of addiction journal editors and their colleagues, it discusses how to write research articles and systematic reviews, choose a journal, respond to reviewers’ reports, become a reviewer, and resolve the often difficult authorship, ethical and citation issues that arise in addiction science publishing. As a “Guide for the Perplexed,” Publishing Addiction Science helps novice as well as experienced researchers to deal with these challenges. It is suitable for university courses and forms the basis of the training workshops offered by the International Society of Addiction Journal Editors (ISAJE). Co-sponsored by ISAJE and the scientific journal Addiction, the third edition of Publishing Addiction Science gives special attention to the challenges faced by researchers from developing and non-English-speaking countries and features new chapters on guidance for clinician-scientists and the growth of infrastructure and career opportunities in addiction science.

Clinical Trials

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.

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