Clinical Trials

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Introduction to Randomized Controlled Clinical Trials, Second Edition
A Guide for Practitioners
Strategies and Challenges
Principles and Practice of Clinical Trial Medicine
Handbook of Neuroemergency Clinical Trials

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Workshop Report John Wiley & Sons
Already popular in the analysis of medical device trials, adaptive Bayesian designs are increasingly being used in drug development for a wide variety of diseases and conditions, from Alzheimer’s disease and multiple sclerosis to obesity, diabetes, hepatitis C, and HIV. Written by leading pioneers of Bayesian clinical trial designs, Bayesian Adaptive Methods for Clinical Trials explores the growing role of Bayesian thinking in the rapidly changing world of clinical trial analysis. The book first summarizes the current state of clinical trial design and analysis and introduces the main ideas and potential benefits of a Bayesian alternative. It then gives an overview of basic Bayesian methodological and computational tools needed for Bayesian clinical trials. With a focus on Bayesian designs that achieve good power and Type I error, the next chapters present Bayesian tools useful in early (Phase I) and middle (Phase II) clinical trials as well as two recent Bayesian adaptive Phase II studies: the BATTLE and ISPY-2 trials. In the following chapter on late (Phase III) studies, the authors emphasize modern adaptive methods and seamless Phase II–III trials for maximizing information usage and minimizing trial duration. They also describe a case study of a recently approved medical device to treat atrial fibrillation. The concluding chapter covers key special topics, such as the proper use of historical data, equivalence studies, and subgroup analysis. For readers involved in clinical trials research, this book significantly updates and expands their statistical toolkits. The authors provide many detailed examples drawing on real data sets. The R and WinBUGS codes used throughout are available on supporting websites. Scott Berry talks about the book on the CRC Press YouTube Channel.
Perspectives on Current Issues John Wiley & Sons
Pharmaceuticals companies, biotech companies, and CROs, regardless of size, all face the same challenge of managing costs and operational execution associated with bringing a valuable drugs and devices to market. Because of timeline pressures and cost as well as the growing interest in "neglected diseases" and diseases affecting the emerging nations, clinical trials are increasingly conducted in emerging markets and developing

countries where infrastructure, leadership, skilled personnel and a governance are at a premium. Working with academics, regulatory professionals, safety officers, experts from the pharma industry and CROs, the editors have put together this up-to-date, step-by-step guide book to building and enhancing global clinical trial capacity in emerging markets and developing countries. This book covers the design, conduct, and tools to build and/or enhance human capacity to execute such trials, appealing to individuals in health ministries, pharmaceutical companies, world health organizations, academia, industry, and non-governmental organizations (NGOs) who are managing global clinical trials. Gives medical professionals the business tools needed to effectively execute clinical trials throughout the world Provides real world international examples which illustrate the practical translation of principles Includes forms, templates, and additional references for standardization in a number of global scenarios

A Methodologic Perspective CRC Press

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.

Designs for Clinical Trials John Wiley & Sons

Clinical TrialsStudy Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH GuidelinesAcademic Press

Data Monitoring in Clinical Trials Academic Press

This comprehensive, unified text on the principles and practice of clinical trials presents a detailed account of how to conduct the trials. It describes the design, analysis, and interpretation of clinical trials in a non-technical manner and provides a general perspective on their historical development, current status, and future strategy. Features examples derived from the author's personal experience.

A Practical Guide to Managing Clinical Trials Cambridge University Press

From the authors of "Fundamentals of Clinical Trials" which has sold over 15,000 copies world wide since its publication in 1998. No competition yet as the text does not focus on how to do clinical trials but on very specific situations that can be encountered during the process.

Clinical Trials in Neurology Springer

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.

Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines John Wiley & Sons

Studies that are unimpeachably thorough, non-political, unbiased, and properly designed... These are the standards to which everyone in clinical research aspires. Yet, the difficulties in designing trials and interpreting data are subtle and ever present. The new edition of Clinical Trials in Oncology provides a concise, nontechnical, and now thoroughly up-to-date review of methods and issues related to clinical trials. The authors emphasize the importance of proper study design, analysis, and data management and identify the major pitfalls that are seemingly inherent in these processes. This edition includes a new section that describes recent innovations in Phase I designs. Another new section on microarray data examines the challenges presented by massive data sets and describes approaches used to meet those challenges. As always, the authors use clear, lucid prose and a multitude of real-world trials as examples to convey the principles of successful trials without the need for a strong statistics or mathematics background. Although the book focuses on cancer trials, the issues and concepts are important in any clinical setting. Clinical Trials in Oncology, Second Edition works to improve the mutual understanding by clinicians and statisticians of the principles of clinical trials and helps them avoid the many hazards that can jeopardize the success of a trial.

Challenges and Opportunities: Proceedings of a Workshop CRC Press

Handbook of Neuroemergency Clinical Trials, Second Edition, focuses on the practice of clinical trials in acute neuroscience populations, or what have been called neuroemergencies. Neuroemergencies are complex, life-threatening diseases and disorders, often with devastating consequences, including death or disability. The overall costs are staggering in terms of annual incidence and costs associated with treatment and survival, yet despite their significance as public health issues, there are few drugs and devices available for definitive treatment. The book focuses on novel therapies and the unique challenges their intended targets pose for the design and analysis of clinical trials.

This volume provides neurologists, neuroscientists, and drug developers with a more complete understanding of the scientific and medical issues of relevance in designing and initiating clinical development plans for novel drugs intended for acute neuroscience populations. The editors provide the best understanding of the pitfalls associated with acute CNS drug development and the best information on how to approach and solve issues that have plagued drug development. Presents a comprehensive overview on clinical trials and drug development challenges in acute neuroscience populations Provides neurologists, neuroscientists and drug developers with a complete understanding of scientific and medical issues related to designing clinical trials Edited by leaders in the field who have designed and managed over 50 neuroemergency clinical trials
Clinical Trials in Oncology, Third Edition Springer Science & Business Media
Presents elements of clinical trial methods that are essential in planning, designing, conducting, analyzing, and interpreting clinical trials with the goal of improving the evidence derived from these important studies This Third Edition builds on the text's reputation as a straightforward, detailed, and authoritative presentation of quantitative methods for clinical trials. Readers will encounter the principles of design for various types of clinical trials, and are then skillfully guided through the complete process of planning the experiment, assembling a study cohort, assessing data, and reporting results. Throughout the process, the author alerts readers to problems that may arise during the course of the trial and provides common sense solutions. All stages of therapeutic development are discussed in detail, and the methods are not restricted to a single clinical application area. The authors bases current revisions and updates on his own experience, classroom instruction, and feedback from teachers and medical and statistical professionals involved in clinical trials. The Third Edition greatly expands its coverage, ranging from statistical principles to new and provocative topics, including alternative medicine and ethics, middle development, comparative studies, and adaptive designs. At the same time, it offers more pragmatic advice for issues such as selecting outcomes, sample size, analysis, reporting, and handling allegations of misconduct. Readers familiar with the First and Second Editions will discover revamped exercise sets; an updated and extensive reference section; new material on endpoints and the developmental pipeline, among others; and revisions of numerous sections. In addition, this book: • Features accessible and broad coverage of statistical design methods—the crucial building blocks of clinical trials and medical research -- now complete with new chapters on overall development, middle development, comparative studies, and adaptive designs • Teaches readers to design clinical trials that produce valid qualitative results backed by rigorous statistical methods • Contains an introduction and summary in each chapter to reinforce key points • Includes discussion questions to stimulate critical thinking and help readers understand how they can apply their newfound knowledge • Provides extensive references to direct readers to the most recent literature, and there are numerous new or revised exercises throughout the book Clinical Trials: A Methodologic Perspective, Third Edition is a textbook accessible to advanced undergraduate students in the quantitative sciences, graduate students in public health and the life sciences, physicians training in clinical research methods, and biostatisticians and epidemiologists. This book is accompanied by downloadable files available below under the DOWNLOADS tab. These files include: MATHEMATICA program – A set of downloadable files that tracks the chapters, containing code pertaining to each. SAS PROGRAMS and DATA FILES used in the book. The following software programs, included in the downloadables, were developed by the author, Steven Piantadosi, M.D., Ph.D: RANDOMIZATION – This program generates treatment assignments for a clinical trial using blocked stratified randomization. CRM – Implements the continual reassessment methods for dose finding clinical trials. OPTIMAL – Calculates two-stage optimal phase II designs using the Simon method. POWER – This is a power and sample size program for clinical trials. Executables for installing these programs can also be found at https://risccweb.csmc.edu/biostats/. Steven Piantadosi, MD, PhD, is the Phase One Foundation Distinguished Chair and Director of the Samuel Oschin Cancer Institute, and Professor of Medicine at Cedars-Sinai Medical Center in Los Angeles, California. Dr. Piantadosi is one of the world's leading experts in the design and analysis of clinical trials for cancer research. He has taught clinical trials methods extensively in formal courses and short venues. He has advised numerous academic programs and collaborations nationally regarding clinical trial design and conduct, and has served on external advisory boards for the National Institutes of Health and other prominent cancer programs and centers. The author of more than 260 peer-reviewed scientific articles, Dr. Piantadosi has published extensively on research results, clinical applications, and trial methodology. While his papers have contributed to many areas of oncology, he has also collaborated on diverse studies outside oncology including lung disease and degenerative neurological disease.
A Practical Guide, Second Edition Wiley-Interscience
A a practical guide to the techniques and issues involved in conducting economic evaluation in ongoing clinical trials, supported with detailed advice on the design and analysis of studies including analysis of cost effectiveness and methodological integrity.
Fundamentals of Clinical Trials CRC Press
Analysis of Clinical Trials Using SAS®: A Practical Guide, Second Edition bridges the gap between modern statistical methodology and real-world clinical trial applications. Tutorial material and step-by-step instructions illustrated with examples from actual trials serve to define relevant statistical approaches, describe their clinical trial applications, and implement the approaches rapidly and efficiently using the power of SAS. Topics reflect the International Conference on Harmonization (ICH) guidelines for the pharmaceutical industry and address important statistical problems encountered in clinical trials. Commonly used methods are covered, including dose-escalation and dose-finding methods that are applied in Phase I and Phase II clinical trials, as well as important trial designs and analysis strategies that are employed in Phase II and Phase III clinical trials, such as multiplicity adjustment, data monitoring, and methods for handling incomplete data. This book also features recommendations from clinical trial experts and a discussion of relevant regulatory guidelines. This new edition includes more examples and case studies, new approaches for addressing statistical problems, and the following new technological updates: SAS procedures used in group sequential trials (PROC SEQDESIGN and PROC SEQTEST) SAS procedures used in repeated measures analysis (PROC GLIMMIX and PROC GEE) macros for implementing a broad range of randomization-based methods in clinical trials, performing complex multiplicity adjustments, and investigating the design and analysis of early phase trials (Phase I dose-escalation trials and Phase II dose-finding trials) Clinical statisticians, research scientists, and graduate students in biostatistics will greatly benefit from the decades of clinical research experience and the ready-to-use SAS macros compiled in this book.
Effective Implementation and Management John Wiley & Sons

Successful drug development relies on accurate and efficient clinical trials to deliver the best and most effective pharmaceuticals and clinical care to patients. However, the current model for clinical trials is outdated, inefficient and costly. Clinical trials are limited by small sample sizes that do not reflect variations among patients in the real world, financial burdens on participants, and slow processes, and these factors contribute to the disconnect between clinical research and clinical practice. On November 28-29, the National Academies of Sciences, Engineering, and Medicine convened a workshop to investigate the current clinical trials system and explore the potential benefits and challenges of implementing virtual clinical trials as an enhanced alternative for the future. This publication summarizes the presentations and discussions from the workshop.

Design, Conduct, Analysis Clinical TrialsStudy Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines Comprehensive book that suggests ways to improve the efficiency of clinical trials and the development of interventions in the neurosciences.

Clinical Trial Design Springer Science & Business Media

Clinical trials have revolutionized the way disease is prevented, detected and treated, and early death avoided, and they continue to be an expanding area of research. They are central to the work of pharmaceutical companies, and there are many academic and public sector organizations that conduct trials on a wide variety of interventions, including drugs, devices, surgical techniques, and changes in behaviour and lifestyle. A Concise Guide to Clinical Trials provides a comprehensive yet easy-to-read overview of the design, conduct and analysis of trials. It requires no prior knowledge on the subject as the important concepts are introduced throughout. There are chapters that distinguish between the different types of trials, and an introduction to systematic reviews, health-related quality of life and health economic evaluation. The book also covers the ethical and legal requirements in setting up a clinical trial due to an increase in governance responsibilities and regulations. This practical guidebook is ideal for busy clinicians and other health professionals who do not have enough time to attend courses or search through extensive textbooks. It will help anyone involved in undertaking clinical research, or those reading about trials. The book is aimed at: Those wishing to learn about clinical trials for the first time, or as a quick reference guide, for example as part of a taught course on clinical trials Health professionals who wish to conduct their own trials, or participate in other people’s studies People who work in pharmaceutical companies, grant funding organisations, or regulatory agencies

Bayesian and Frequentist Adaptive Methods National Academies Press

A Practical Guide to Managing Clinical Trials is a basic, comprehensive guide to conducting clinical trials. Designed for individuals working in research site operations, this user-friendly reference guides the reader through each step of the clinical trial process from site selection, to site set-up, subject recruitment, study visits, and to study close-out. Topics include staff roles/responsibilities/training, budget and contract review and management, subject study visits, data and document management, event reporting, research ethics, audits and inspections, consent processes, IRB, FDA regulations, and good clinical practices. Each chapter concludes with a review of key points and knowledge application. Unique to this book is "A View from India," a chapter-by-chapter comparison of clinical trial practices in India versus the U.S. Throughout the book and in Chapter 10, readers will glimpse some of the challenges and opportunities in the emerging and growing market of Indian clinical trials.

Concept and Methodologies John Wiley & Sons

This is the fifth edition of a very successful textbook on clinical trials methodology, written by recognized leaders who have long and extensive experience in all areas of clinical trials. The three authors of the first four editions have been joined by two others who add great expertise.Most chapters have been revised considerably from the fourth edition.A chapter on regulatory issues has been included and the chapter on data monitoring has been split into two and expanded. Many contemporary clinical trial examples have been added.There is much new material on adverse events, adherence, issues in analysis, electronic data, data sharing and international trials. This book is intended for the clinical researcher who is interested in designing a clinical trial and developing a protocol. It is also of value to researchers and practitioners who must critically evaluate the literature of published clinical trials and assess the merits of each trial and the implications for the care and treatment of patients. The authors use numerous examples of published clinical trials to illustrate the fundamentals. The text is organized sequentially from defining the question to trial closeout. One chapter is devoted to each of the critical areas to aid the clinical trial researcher. These areas include pre-specifying the scientific questions to be tested and appropriate outcome measures, determining the organizational structure, estimating an adequate sample size, specifying the randomization procedure, implementing the intervention and visit schedules for participant evaluation, establishing an interim data and safety monitoring plan, detailing the final analysis plan and reporting the trial results according to the pre-specified objectives. Although a basic introductory statistics course is helpful in maximizing the benefit of this book, a researcher or practitioner with limited statistical background would still find most if not all the chapters understandable and helpful. While the technical material has been kept to a minimum, the statistician may still find the principles and fundamentals presented in this text useful.This book has been successfully used for teaching courses in clinical trial methodology. "

A Concise Guide to Clinical Trials John Wiley & Sons Incorporated

Clinical trials remain the most important vehicle for improving the care of cancer patients. This text presents the fundamental components and challenges involving clinical investigations. Leading experts discuss the critical issues covering the spectrum of important topics from planning to application. The book has a foreword by Samuel A. Wells, Jr., MD, Professor of Surgery, Duke University Medical Center, Durham, NC, former Director of the American College of Surgeons and Founder of the American College of Surgeons Oncology Group.

Developing a National Registry of Pharmacologic and Biologic Clinical Trials SAS Institute

Clinical trials are an important part of medicine and healthcare today, deciding which treatments we use to treat patients. Anyone involved in healthcare today must know the basics of running and interpreting clinical trial data. Written in an easy-to-understand style by authors who have considerable expertise and experience in both academia and industry, Principles and Practice of Clinical Trial Medicine covers all of the basics of clinical trials, from legal and ethical issues to statistics, to patient recruitment and reporting results. Jargon-free writing style enables those with less experience to run their own clinical trials and interpret data Book contains an ideal mix of theory and practice so researchers will understand both the rationale and logistics to clinical trial medicine Expert authorship whose experience includes running clinical trials in an academic as well as industry settings

Numerous illustrations reinforce and elucidate key concepts and add to the book's overall pedagogy

Clinical Trials Academic Press

This second revised and updated edition is a practical handbook on clinical trials in the growing field of osteoporosis. Topics covered include study design, technical issues, data collection, quality assurance, data analysis, and presentation. Clinical Trials in Osteoporosis takes the user through the process step-by-step from start to finish. It also provides a background on regulatory guidelines, ethical implications, endpoints, current therapies, and the ideal drug to use. It will serve as a practical manual for clinicians and scientists new to the subject and provide a standard for existing centers to measure themselves against.