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Fundamentals of Clinical Trials Sharing Clinical Trial Data **Principles and Practice of Clinical Research** Designing Clinical Research **Fundamentals of Clinical Trials** *Sample Size Tables for Clinical Studies* **Textbook of Clinical Trials in Oncology** *The CRC's Guide to Coordinating Clinical Research* **The Prevention and Treatment of Missing Data in Clinical Trials Statistics Applied to Clinical Trials** *Integrating Clinical Research into Epidemic Response* Field Trials of Health Interventions *Designing Clinical Research Clinical Research Coordinator Handbook* Atkinson's Principles of Clinical Pharmacology **Histopathology of Preclinical Toxicity Studies Good Practice of Clinical Drug Trials Publishing and Presenting Clinical Research Medical Biostatistics Textbook of Clinical Trials Encyclopedia of Biopharmaceutical Statistics, Third Edition Platelets Critical Appraisal of Epidemiological Studies and Clinical Trials Proceedings of the Fourth Seattle Symposium in Biostatistics: Clinical Trials Statistical Methods in Medical Research** Anticancer Drug Development **Data Monitoring Committees in Clinical Trials Bad Pharma** Statistics in Medicine The CRA's Guide to Monitoring Clinical Research **Design and Analysis of Clinical Trials Review of the Fialuridine (FIAU) Clinical Trials** *Goodman's Basic Medical Endocrinology Wiley Encyclopedia of Clinical Trials, 4 Volume Set* **Design and Analysis of Clinical Trials Successful Drug Discovery, Volume 4 Contemporary Practice in Clinical Chemistry Clinical Trials in Oncology, Third Edition** Drug Information **Foundations of Clinical Research**

The randomized control clinical trial has become the gold standard scientific method for the evaluation of pharmaceuticals, biologics, devices, procedures and diagnostic tests. This trial design has been successfully used in both therapeutic and disease prevention trials. It is superior to alternative designs by eliminating several sources of bias which exist in those designs. This role has evolved over the past three decades in a number of disease areas including cardiology, opthalmology, cancer and AIDS. While the specifics of using the randomized control design for a specific intervention and disease may differ, the basic fundamentals still apply in developing the study protocol and operational procedures. These fundamentals still apply in developing the study protocol and operational procedures. These fundamentals include identifying the specific questions to be tested and appropriate outcome measures, determining an adequate sample size, specifying the randomization procedure, detailing the intervention with visit schedules for subject evaluation, establishing an interim data and safety monitoring plan, detailing the final analysis plan and determining the organizational structure.This text is structured to address the fundamentals as the protocol for a clinical trial is being developed. A chapter is devoted to each of the critical areas of a protocol to aid the clinical trial researcher. The fundamentals described in this text are based on sound scientific methodology, statistical principles and years of accumulated experience by the three authors. Collectively, the authors have been active researchers in a broad area of clinical trials including cardiology, cancer, opthalmology, diabetes, osteoporosis, AIDS, women's health and screening tests. In these studies, the authors have served as members of the steering committee responsible for developing the protocol and as members of data and safety monitoring committees. The fundamentals were proposed in the first edition published in 1981 and have not changed substantially in the later editions. However, the number of examples illustrating the fundamentals has greatly expanded base on the collective experience of the authors.This text is intended for the clinical researcher who is interested in designing a clinical trial and developing a protocol. It is also of value to researchers and practitioners who must critically evaluate the literature of published clinical trials and assess the merits of each trial and the implications for the care and treatment of patients. The test uses numerous examples of published clinical trials from a variety of medical disciples to meaningfully illustrate the fundamentals. Technical design issues such as sample size are considered but the technical details have been suppressed as much as possible through the use of graphs and tables. While the technical material has been kept to a minimum, the statistician may still find the principles and fundamentals presented in this text useful both in a consulting and teaching capacity.The text assumes that the readers have only a modest formal statistical background. A basic introductory statistics course is helpful in maximizing the benefit of the text. However, a researcher or practitioner with no statistical background would still find most, if not all the chapters understandable and useful. Goodman's Basic Medical Endocrinology, Fifth Edition, has been student tested and approved for decades. This essential textbook provides up-to-date coverage of rapidly unfolding advances in the understanding of hormones involved in regulating most aspects of bodily functions. It is richly illustrated in full color with both descriptive schematic diagrams and laboratory findings obtained in clinical studies. This is a classic reference for moving forward into advanced study. Clinical case studies in every chapter E-book version available with every copy for obtaining images and tables for lectures or notes Clinicians added as co-authors to enhance usefulness by physicians and medical students and residents Detailed molecular biology of hormones and hormone action for graduate and advanced undergraduate students Expanded and updated color images emphasizing hormone action at the molecular level In-depth molecular biology and clinical sections boxed for ease of access 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 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. 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. " Designing Clinical Research sets the standard for providing a practical guide to planning, tabulating, formulating, and implementing clinical research, with an easy-to-read, uncomplicated presentation. This edition incorporates current research methodology—including molecular and genetic clinical research—and offers an updated syllabus for conducting a clinical research workshop. Emphasis is on common sense as the main ingredient of good science. The book explains how to choose well-focused research questions and details the steps through all the elements of study design, data collection, quality assurance, and basic grant-writing. All chapters have been thoroughly revised, updated, and made more user-friendly. "IEA, International Epidemiological Association, Welcome Trust." The third edition of the bestselling Clinical Trials in Oncology provides a concise, nontechnical, and thoroughly up-to-date review of methods and issues related to cancer clinical trials. The authors emphasize the importance of proper study design, analysis, and data management and identify the pitfalls inherent in these processes. In addition, the book has been restructured to have separate chapters and expanded discussions on general clinical trials issues, and issues specific to Phases I, II, and III. New sections cover innovations in Phase I designs, randomized Phase II designs, and overcoming the challenges of array data. Although this book focuses on cancer trials, the same issues and concepts are important in any clinical setting. As always, the authors use clear, lucid prose and a multitude of real-world examples to convey the principles of successful trials without the need for a strong statistics or mathematics background. Armed with Clinical Trials in Oncology, Third Edition, clinicians and statisticians can avoid the many hazards that can jeopardize the success of a trial. Histopathological assessment of tissue sections is an important componant of many preclinical studies which are conducted to support the safety and clinical development of novel therapeutic agents for use in the treatment of human diseases. The drug discovery process, aided by modern biotechnology, is now capable of generating highly potent, pharmacologically active agents which can give rise to quite unusual constellations of tissue pathology. The complexity and the number of histopathological findings in individual studies indicate the need for lucididy in descriptions and conclusions. In the light of these and other difficulties, this text is aimed towards bringing together into one volume a description of histopathological changes which relate to toxicity testing of therapeutic agents in the usual test species: rat, mouse, dog and non-human primate. This book is an excellent starting point for the analysis of drug-induced findings in toxicity studies. In June 1993 a clinical trial of fialuridine (FIAU), a promising new medication for hepatitis B, was abruptly terminated when one of the 15 out-patients participating in the National Institutes of Health (NIH) study was suddenly hospitalized with liver failure. Although all the remaining patients were contacted and told to stop taking their medication, six more subsequently developed severe toxicity. Five patients died, and two others were probably saved from death only by having liver transplants. In response to a request from the Secretary of the Department of Health and Human Services, the IOM committee has analyzed the FIAU clinical trials, making recommendations for additional safeguards for the conduct of future clinical trials. This evaluation included the review of documents pertaining to investigational new drug submissions, protocols and consent forms from other clinical trials, as well as information available from other clinical and preclinical experience with compounds related to FIAU and its parent drug, fiacitibine (FIAC), which is metabolized to FIAU. The committee does not seek to affix responsibility for the adverse outcome of this NIH trial, but instead focuses on whether any rules or procedures governing the clinical trials process itself need to be changed, and if so, what burdens or costs such changes might place on future clinical trials. In this revised third edition of the essential reference for clinical research coordinators (CRCs), Deborrah Norris provides expanded coverage of CRC duties and regulatory requirements, including new sections on investigator responsibilities, data clarification, and adverse event reporting. The book's five appendices include a directory of CRC resources, updated forms and checklists, state regulatory requirements and contact information, conversion charts and tables, a glossary, and more. Randomized clinical trials are the primary tool for evaluating new medical interventions. Randomization provides for a fair comparison between treatment and control groups, balancing out, on average, distributions of known and unknown factors among the participants. Unfortunately, these studies often lack a substantial percentage of data. This missing data reduces the benefit provided by the randomization and introduces potential biases in the comparison of the treatment groups. Missing data can arise for a variety of reasons, including the inability or unwillingness of participants to meet appointments for evaluation. And in some studies, some or all of data collection ceases when participants discontinue study treatment. Existing guidelines for the design and conduct of clinical trials, and the analysis of the resulting data, provide only limited advice on how to handle missing data. Thus, approaches to the analysis of data with an appreciable amount of missing values tend to be ad hoc and variable. The Prevention and Treatment of Missing Data in Clinical Trials concludes that a more principled approach to design and analysis in the presence of missing data is both needed and possible. Such an approach needs to focus on two critical elements: (1) careful design and conduct to limit the amount and impact of missing data and (2) analysis that makes full use of information on all randomized participants and is based on careful attention to the assumptions about the nature of the missing data underlying estimates of treatment effects. In addition to the highest priority recommendations, the book offers more detailed recommendations on the conduct of clinical trials and techniques for analysis of trial data. Encyclopedic in breadth, yet practical and concise, Medical Biostatistics, Fourth Edition focuses on the statistical aspects ofmedicine with a medical perspective, showing the utility of biostatistics as a tool to manage many medical uncertainties. This edition includes more topics in order to fill gaps in the previous edition. Various topics have been enlarged and modified as per the new understanding of the subject. Provides unique insider insight into the current drug development process, and what it takes to achieve success In this fourth volume in the series, inventors and primary developers of drugs that made it to the market continue telling the story of the drugs? discovery and development, and discuss the sometimes twisted route from the first drug candidate molecule to the final marketed one. Beginning with a general section addressing overarching topics for drug discovery, the book offers seven chapters that feature selected case studies describing recently introduced drugs or drug classes. These include small molecule drugs as well as biopharmaceuticals and range across different therapeutic fields. Together, they provide a representative cross-section of the present-day drug development effort. Successful Drug Discovery: Volume 4 covers trends in peptide-based drug discovery and the physicochemical properties of recently approved oral drugs. The section on drug class studies looks at antibody-drug conjugates and the discovery, evolution, and therapeutic potential of dopamine partial agonists. Featured case studies examine the discovery of Etelcalcetide for the treatment of secondary hyper-parathyroidism in patients with chronic kidney disease; the development of Lenvatinib Mesylate; the discovery and development of Venetoclax; and more. -Focuses on recently introduced drugs that have not been featured in any textbooks or general references, including Ocrelizumab, a new generation of anti-CD-20 mAb for the treatment of multiple sclerosis, and Venetoclax, a selective antagonist of BCL-2 -Features personal experiences of successful drug developers from industry and academia -Endorsed and supported by the International Union of Pure and Applied Chemistry (IUPAC) Successful Drug Discovery: Volume 4 provides a fascinating and informative look into the process of drug discovery and would be a great reference for those in the pharmaceutical industry, organic and pharmaceutical chemists, and lecturers in pharmacy. Everything pharmacists need to know about drug information management Drug Information: A Guide for Pharmacists, Fourth Edition teaches students and professionals how to research, interpret, evaluate, collate, and disseminate drug information in the most effective and efficient manner possible. Updated throughout, the book also addresses other important issues such as the legal and ethical considerations of providing information, how to respond to requests for information, and how to determine what information should be made available. Drug Information: A Guide for Pharmacists, Fourth Edition covers essential topics such as: Formulating effective responses and recommendations for information Evaluation of drug literature The application of statistical analysis in the biomedical sciences Drug evaluation monographs Adverse drug reactions Medication and patient safety Investigational drugs New to

this edition: Five new chapters: “Policy Development, Project Design, and Implementation,” “Drug Information in Ambulatory Care,” “Drug Information and Contemporary Community Pharmacy Practice,” “Drug Information Education and Training,” and “Pharmaceutical Industry and Regulatory Affairs: Opportunities for Drug Information Specialists” Key Concepts have been added to the beginning of each chapter and are identified with icons in the chapter text Case Studies and multiple-choice questions have been added to most chapters Twenty-two appendices include: Drug Consultation Request Form, Performing a PubMed® Search, Questions for Assessing Clinical Trials, and Questions to Consider for Critique of Primary Literature. 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 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. Contemporary Practice in Clinical Chemistry, Fourth Edition, provides a clear and concise overview of important topics in the field. This new edition is useful for students, residents and fellows in clinical chemistry and pathology, presenting an introduction and overview of the field to assist readers as they in review and prepare for board certification examinations. For new medical technologists, the book provides context for understanding the clinical utility of tests that they perform or use in other areas in the clinical laboratory. For experienced laboratorians, this revision continues to provide an opportunity for exposure to more recent trends and developments in clinical chemistry. Includes enhanced illustration and new and revised color figures Provides improved self-assessment questions and end-of-chapter assessment questions This book provides statisticians and researchers with the statistical tools - equations, formulae and numerical tables - to design and plan clinical studies and carry out accurate, reliable and reproducible analysis of the data so obtained. There is no way around this as incorrect procedure in clinical studies means that the researcher's paper will not be accepted by a peer-reviewed journal. Planning and analysing clinical studies is a very complicated business and this book provides indispensible factual information. Please go to http://booksupport.wiley.com and enter 9781405146500 to easily download the supporting materials. In 1948 the first randomized controlled trial was published by the English Medical Research Council in the British Medical Journal. Until then, observations had been uncontrolled. Initially, trials frequently did not confirm the hypotheses to be tested. This phenomenon was attributed to low sensitivity due to small samples, as well as inappropriate hypotheses based on biased prior trials. Additional flaws were recognized and, subsequently, were better accounted for: carryover effects due to insufficient washout from previous treatments, time effects due to external factors and the natural history of the condition under study, bias due to asymmetry between treatment groups, lack of sensitivity due to a negative correlation between treatment responses, and so on. Such flaws, mainly of a technical nature, have been largely corrected and led to trials after 1970 being of significantly higher quality. The past decade has focused, in addition to technical aspects, on the need for circumspection in the planning and conducting of clinical trials. As a consequence, prior to approval, clinical trial protocols are now routinely scrutinized by different circumstantial organs, including ethics committees, institutional and federal review boards, national and international scientific organizations, and monitoring committees charged with conducting interim analyses. This book not only explains classical statistical analyses of clinical trials, but also addresses relatively novel issues, including equivalence testing, interim analyses, sequential analyses, and meta-analyses, and provides a framework of the best statistical methods currently available for such purposes. This book is not only useful for investigators involved in the field of clinical trials, but also for all physicians who wish to better understand the data of trials as currently published. This volume contains a selection of chapters base on papers presented at the Fourth Seattle Symposium in Biostatistics: Clinical Trials. The symposium was held in 2010 to celebrate the 40th anniversary of the University of Washington School of Public Health and Community Medicine. It featured keynote lectures by David DeMets and Susan Ellenberg and 16 invited presentations by other prominent researchers. The papers contained in this volume encompass recent methodological advances in several important clinical trials research, such as biomarkers, meta-analyses, sequential and adaptive clinical trials, and various genetic bioinformatic techniques. This volume will be a valuable reference for researchers and practitioners in the field of clinical trials. 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. We like to imagine that medicine is based on evidence and the results of fair testing and clinical trials. In reality, those tests and trials are often profoundly flawed. We like to imagine that doctors who write prescriptions for everything from antidepressants to cancer drugs to heart medication are familiar with the research literature about a drug, when in reality much of the research is hidden from them by drug companies. We like to imagine that doctors are impartially educated, when in reality much of their education is funded by the pharmaceutical industry. We like to imagine that regulators have some code of ethics and let only effective drugs onto the market, when in reality they approve useless drugs, with data on side effects casually withheld from doctors and patients. All these problems have been shielded from public scrutiny because they're too complex to capture in a sound bite. But Ben Goldacre shows that the true scale of this murderous disaster fully reveals itself only when the details are untangled. He believes we should all be able to understand precisely how data manipulation works and how research misconduct in the medical industry affects us on a global scale. With Goldacre's characteristic flair and a forensic attention to detail, Bad Pharma reveals a shockingly broken system and calls for regulation. This is the pharmaceutical industry as it has never been seen before. This book presents a logical system of critical appraisal, to allow readers to evaluate studies and to carry out their own studies more effectively. This system emphasizes the central importance of cause and effect relationships. Its great strength is that it is applicable to a wide range of issues, and both to intervention trials and observational studies.

This system unifies the often different approaches used in epidemiology, health services research, clinical trials, and evidence-based medicine, starting from a logical consideration of cause and effect. The author's approach to the issues of study design, selection of subjects, bias, confounding, and the place of statistical methods has been praised for its clarity and interest. Systematic reviews, meta-analysis, and the applications of this logic to evidence-based medicine, knowledge-based health care, and health practice and policy are discussed. Current and often controversial examples are used, including screening for prostate cancer, publication bias in psychiatry, public health issues in developing countries, and conflicts between observational studies and randomized trials. Statistical issues are explained clearly without complex mathematics, and the most useful methods are summarized in the appendix. The final chapters give six applications of the critical appraisal of major studies: randomized trials of medical treatment and prevention, a prospective and a retrospective cohort study, a small matched case-control study, and a large case-control study. In these chapters, sections of the original papers are reproduced and the original studies placed in context by a summary of current developments. Draw upon the foundations necessary for finding and interpreting research evidence across all healthcare professions. Revised to reflect the most current changes in the field of clinical research in rehabilitation and medicine, you'll find a growing emphasis on evidence-based practice (EBP) as well as new vocabulary that is being integrated into research and practice across disciplines. Praise for the Second Edition: “...a grand feast for biostatisticians. It stands ready to satisfy the appetite of any pharmaceutical scientist with a respectable statistical appetite.” —Journal of Clinical Research Best Practices The Third Edition of Design and Analysis of Clinical Trials provides complete, comprehensive, and expanded coverage of recent health treatments and interventions. Featuring a unified presentation, the book provides a well-balanced summary of current regulatory requirements and recently developed statistical methods as well as an overview of the various designs and analyses that are utilized at different stages of clinical research and development. Additional features of this Third Edition include: • New chapters on biomarker development and target clinical trials, adaptive design, trials for evaluating diagnostic devices, statistical methods for translational medicine, and traditional Chinese medicine • A balanced overview of current and emerging clinical issues as well as newly developed statistical methodologies • Practical examples of clinical trials that demonstrate everyday applicability, with illustrations and examples to explain key concepts • New sections on bridging studies and global trials, QT studies, multinational trials, comparative effectiveness trials, and the analysis of QT/QTc prolongation • A complete and balanced presentation of clinical and scientific issues, statistical concepts, and methodologies for bridging clinical and statistical disciplines • An update of each chapter that reflects changes in regulatory requirements for the drug review and approval process and recent developments in statistical design and methodology for clinical research and development Design and Analysis of Clinical Trials, Third Edition continues to be an ideal clinical research reference for academic, pharmaceutical, medical, and regulatory scientists/researchers, statisticians, and graduate-level students. 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 PLATELETS is the definitive current source of state-of-the-art knowledge about platelets and covers the entire field of platelet biology, pathophysiology, and clinical medicine. Recently there has been a rapid expansion of knowledge in both basic biology and the clinical approach to platelet-related diseases including thrombosis and hemorrhage. Novel platelet function tests, drugs, blood bank storage methods, and gene therapies have been incorporated into patient care or are in development. This book draws all this information into a single, comprehensive and authoritative resource. · First edition won Best Book in Medical Science Award from the Association of American Publishers · Contains fourteen new chapters on topics such as platelet genomics and proteomics, inhibition of platelet function by the endothelium, clinical tests of platelet function, real time in vivo imaging of platelets, and inherited thrombocytopenias · A comprehensive full color reference comprising over 70 chapters, 1400 pages, and 16,000 references In recent years, there has been an explosive growth of biopharmaceutical and clinical research, including the development of new medicines for treating severe or life-threatening diseases. Biopharmaceutical statistics plays an extremely important role in ensuring not only the efficacy and safety of the medicine under investigation, but also that the pharmaceutical product possesses good drug characteristics, such as identity, strength, purity, quality, stability, and reproducibility. Widely used by pharmaceutical scientists, clinical researchers, and biostatistics, the Encyclopedia of Biopharmaceutical Statistics, Third Edition is an essential resource on the evolving state of this important field. New to the Third Edition 89 new chapters, bringing the total number of chapters to 230 Updated information on changes in regulatory requirements for drug review/approval processes Recent developments in statistical design and methodology Important topics, including adaptive design in clinical research, translational medicine, statistical genetics, biomarker development, target clinical trials, follow-on biologics, and traditional Chinese medicine Medicine deals with treatments that work often but not always, so treatment success must be based on probability. Statistical methods lift medical research from the anecdotal to measured levels of probability. This book presents the common statistical methods used in 90% of medical research, along with the underlying basics, in two parts: a textbook section for use by students in health care training programs, e.g., medical schools or residency training, and a reference section for use by practicing clinicians in reading medical literature and performing their own research. The book does not require a significant level of mathematical knowledge and couches the methods in multiple examples drawn from clinical medicine, giving it applicable context. Easy-to-follow format incorporates medical examples, step-by-step methods, and check yourself exercises Two-part design features course material and a professional reference section Chapter summaries provide a review of formulas, method algorithms, and check lists Companion site links to statistical databases that can be downloaded and used to perform the exercises from the book and practice statistical methods New in this Edition: New chapters on: multifactor tests on means of continuous data, equivalence testing, and advanced methods New topics include: trial randomization, treatment ethics in medical research, imputation of missing data, and making evidence-based medical decisions Updated database coverage and additional exercises Expanded coverage of numbers needed to treat and to benefit, and regression analysis including stepwise regression and Cox regression Thorough discussion on required sample size This new edition of `Good Practice' is a totally revised and expanded version of this work. It takes into account the new quality guidelines, in particular those listed in the European Union Directive, the application texts and the recommendations of the International Conference on Harmonisation (ICH). It is a practical manual to help you conduct your clinical trials. Many new or revised concepts have been included, in particular: - Rationale for each rule presented - Safety of data in clinical trials - Protection of personal data - Conflicts of interest - Measures to be taken in case of suspected fraud There has been substantial growth in the use of data monitoring committees in recent years, by both government agencies and the pharmaceutical industry. This growth has been brought about by increasing recognition of the value of such committees in safeguarding trial participants as well as protecting trial integrity and the validity of conclusions. This very timely book describes the operation of data monitoring committees, and provides an authoritative guide to their establishment, purpose and responsibilities. * Provides a practical overview of data monitoring in clinical trials. * Describes the purpose, responsibilities and operation of data monitoring committees. * Provides directly applicable advice for those managing and conducting clinical trials, and those serving on data monitoring committees. * Gives insight into clinical data monitoring to those sitting on regulatory and ethical committees. * Discusses issues pertinent to those working in clinical trials in both the US and Europe. The practical guidance provided by this book will be of use to professionals working in and/or managing clinical trials, in academic, government and industry settings, particularly medical statisticians, clinicians, trial co-ordinators, and those working in regulatory affairs and bioethics. 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. Here in a single source is a complete spectrum of ideas on the development of new anticancer drugs. Containing concise reviews of multidisciplinary fields of research, this book offers a wealth of ideas on current and future molecular targets for drug design, including signal transduction, the cell division cycle, and programmed cell death. Detailed descriptions of sources for new drugs and methods for testing and clinical trial design are also provided. One work that can be consulted for all aspects of anticancer drug development Concise reviews of research fields, combined with practical scientific detail, written by internationally respected experts A wealth of ideas on current and future molecular targets for drug design, including signal transduction, the cell division cycle, and programmed cell death Detailed descriptions of the sources of new anticancer drugs, including combinatorial chemistry, phage display, and natural products Discussion of how new drugs can be tested in preclinical systems, including the latest technology of robotic assay systems, cell culture, and experimental animal techniques Hundreds of references that allow the reader to access relevant scientific and medical literature Clear illustrations, some in color, that provide both understanding of the field and material for teaching This monumental reference on all facets of clinical trials provides comprehensive coverage and emphasis on clearly stated and defined concepts, methodologies, and applications. With more than 450entries, from 350 of the world's leading experts in the field in academic and corporate settings, Encyclopedia of Clinical Trials is a world-class and one-of-a-kind compendia of basic concepts, methodologies, and applications in clinical trials. It includes coverage of: overview and basic statistical concepts; concepts of design and analysis of clinical trials; and methodologies and issues for clinical data analysis. This guidebook is filled with valuable information on the role and responsibilities of a clinical research coordinator (CRC) and explains the research process from the site and CRC perspective. Topics covered include: identifying the regulations governing clinical research; describing the drug development process; discussing good clinical practices and how to apply them in clinical trials and organizing a clinical practice. 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. "This book provides a practical guide to planning, tabulating, formulating, and implementing clinical research, in an easy-to-use, readable presentation"--Provided by publisher.

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