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Publishing and Presenting Clinical Research *Publishing and Presenting Clinical Research Designing Clinical Research* Sharing Clinical Trial Data **Publishing Your Medical Research Women in Ophthalmology** *Fundamentals of Clinical Trials* **Transforming Clinical Research in the United States Clinical Research Transformed** *Textbook of Clinical Trials* **Missing Data in Clinical Studies Presenting Medical Statistics from Proposal to Publication** Ethical Conduct of Clinical Research Involving Children *Essentials of Clinical Research Targeted Regulatory Writing Techniques: Clinical Documents for Drugs and Biologics Mixed Methods in Health Sciences Research* Design and Analysis of Clinical Trials *The Comprehensive Guide To Clinical Research* Clinical Research Informatics **Testing Treatments The Millon Clinical Multiaxial Inventory** Handbook for Clinical Research Clinical Trials **Sample Size Calculations in Clinical Research** *Presenting Medical Statistics from Proposal to Publication* Designing Clinical Research *Clinical Hematology and Oncology* **Nursing Research** Qualitative Research **Clinical Evaluation of Dental Materials Design and Analysis of Clinical Trials Global Clinical Trials Playbook Sharing Clinical Research Data** *Clinical Obstetrics and Gynaecology E-Book* **Introduction to Statistical Methods for Clinical Trials Medical Apartheid Principles and Practice of Clinical Trials** *Dan Shen (Salvia miltiorrhiza) in Medicine Conflict of Interest in Medical Research, Education, and Practice* An Introduction to Clinical Research for Health and Social Care Professionals

As many medical and healthcare researchers have a love-hate relationship with statistics, the second edition of this practical reference book may make all the difference. Using practical examples, mainly from the authors' own research, the book explains how to make sense of statistics, turn statistical computer output into coherent information, and help decide which pieces of information to report and how to present them. The book takes you through all the stages of the research process, from the initial research proposal, through ethical approval and data analysis, to reporting on and publishing the findings. Helpful tips and information boxes, offer clear guidance throughout, including easily followed instructions on how to: -develop a quantitative research proposal for ethical/institutional approval or research funding -write up the statistical aspects of a paper for publication -choose and perform simple and more advanced statistical analyses -describe the statistical methods and present the results of an analysis. This new edition covers a wider range of statistical programs - SAS, STATA, R, and SPSS, and shows the commands needed to obtain the analyses and how to present it, whichever program you are using. Each specific example is annotated to indicate other scenarios that can be analysed using the same methods, allowing you to easily transpose the knowledge gained from the book to your own research. The principles of good presentation are also covered in detail, from translating relevant results into suitable extracts, through to randomised controlled trials, and how to present a meta-analysis. An added ingredient is the inclusion of code and datasets for all analyses shown in the book on our website (http://medical-statistics.info). Written by three experienced biostatisticians based in the UK and US, this is a step-by-step guide that will be invaluable to researchers and postgraduate students in medicine, those working in the professions allied to medicine, and statisticians in consultancy roles. Collaborations of physicians and researchers with industry can provide valuable benefits to society, particularly in the translation of basic scientific discoveries to new therapies and products. Recent reports and news stories have, however, documented disturbing examples of relationships and practices that put at risk the integrity of medical research, the objectivity of professional education, the quality of patient care, the soundness of clinical practice guidelines, and the public's trust in medicine. Conflict of Interest in Medical Research, Education, and Practice provides a comprehensive look at conflict of interest in medicine. It offers principles to inform the design of policies to identify, limit, and manage conflicts of interest without damaging constructive collaboration with industry. It calls for both short-term actions and long-term commitments by institutions and individuals, including leaders of academic medical centers, professional societies, patient advocacy groups, government agencies, and drug, device, and pharmaceutical companies. Failure of the medical community to take convincing action on conflicts of interest invites additional legislative or regulatory measures that may be overly broad or unduly burdensome. Conflict of Interest in Medical Research, Education, and Practice makes several recommendations for strengthening conflict of interest policies and curbing relationships that create risks with little benefit. The book will serve as an invaluable resource for individuals and organizations committed to high ethical standards in all realms of medicine. 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 explains statistics specifically for a medically literate audience. Readers gain not only an understanding of the basics of medical statistics, but also a critical insight into how to review and evaluate clinical trial evidence. This book describes the authors’ standard or ‘best’ practices used in writing regul- ed clinical documents for the drug and biologics industry. The fundamental premise of this book is that the end (documents submitted to a health authority) is dep- dent on the beginning (the planning and strategy that go into organizing written documentation). Each regulatory document inherently exists within a constellation of related documents. This book attempts to show the relationships between and among these documents and suggests strategies for organizing and writing these documents to maximize ef?ciency while developing clear and concise text. At all times, and irrespective of applicable laws and guidelines, good communication skills and a sense of balance are essential to adequately, accurately, and clearly describe a product’s characteristics. At no time should the reader perceive these suggestions to be the only viable solution to writing regulatory documents nor should the reader expect that these suggestions guarantee product success. The audience for this book is the novice medical writer, or those who would like to explore or enhance regulatory-writing skills. We assume the reader will have a basic understanding of written communication, but little experience in applying this skill to the task of regulatory writing. Extensive knowledge of science, clinical me- cine, mathematics, or regulatory affairs law is not required to use the best practices described in this book. In recent decades, advances in biomedical research have helped save or lengthen the lives of children around the world. With improved therapies, child and adolescent mortality rates have decreased significantly in the last half century. Despite these advances, pediatricians and others argue that children have not shared equally with adults in biomedical advances. Even though we want children to benefit from the dramatic and accelerating rate of progress in medical care that has been fueled by scientific research, we do not want to place children at risk of being harmed by participating in clinical studies. Ethical Conduct of Clinical Research Involving Children considers the necessities and challenges of this type of research and reviews the ethical and legal standards for conducting it. It also considers problems with the interpretation and application of these standards and conduct, concluding that while children should not be excluded from potentially beneficial clinical studies, some research that is ethically permissible for adults is not acceptable for children, who usually do not have the legal capacity or maturity to make informed decisions about research participation. The book looks at the need for appropriate pediatric expertise at all stages of the design, review, and conduct of a research project to effectively implement policies to protect children. It argues persuasively that a robust system for protecting human research participants in general is a necessary foundation for protecting child research participants in particular. 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 Mixed Methods in Health Sciences Research: A Practical Primer, by Leslie Curry and Marcella Nunez-Smith, presents key theories, concepts, and approaches in an accessible way. Packed with illustrations from the health sciences literature, this ready-to-use guidebook shows readers how to design, conduct, review, and use mixed methods research findings. Helpful checklists, figures, tables, templates, and much more give readers examples that will elevate the quality of their research, facilitate communication about their methods, and improve efficiency over the course of their projects. Real-world examples and insights from mixed methods researchers provide unique perspectives on every aspect of mixed methods research. This book successfully pulls together foundational mixed methods principles, synthesizes the knowledge base in the field, and translates it for a health science researcher audience. “The content is highly applicable to real life research teams in the areas of clinical research, health services research, and implementation science, providing sound content and practical advice. The authors have synthesized and pull key concepts from a variety of sources to provide a concise resource.” —Linda M. Herrick, South Dakota State University “Everything from the references, to the topics, checklists, conceptual graphic representations, and organizers, interviews, and resources, all contribute to the content and aid with understanding and/or application. … It addresses specific MM research as it pertains to health sciences in a way that other texts just do not even attempt.” —Denise L. Winsor, University of Memphis “[This text is] a very pragmatic approach to mixed methods research; excellent resources, tables, and figures [are] provided, along with cases and examples of value to researchers and grant reviewers. Its relevance to practice, education, and research, as well as to potential policy implications, is a strong focus that would make this a valued textbook for any researcher!” ? —Karen Devereaux Melillo, University of Massachusetts Lowell “The text is cutting edge. It leads the way with its focus on team dynamics. [The authors] succeed in making the book relevant and practical. They also articulate a number of key insights in the area of mixed methods that rarely get addressed, such as teams and conflict. Great read with a lot of good, practical information for mixed methods researchers at all levels. The practical approach of this text makes it an innovative and valuable resource.” —John G. Schumacher, University of Maryland 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. Qualitative Research: Analyzing Life presents a fresh approach to teaching and learning qualitative methods for social inquiry—one that focuses on analysis from the very beginning of the text. By exploring qualitative research through a unique analytic lens, then cumulatively elaborating on methods in each successive chapter, this innovative work cultivates a skill set and literacy base that prepares readers to work strategically with empirical materials in their own fieldwork. Renowned authors Johnny Saldaña and Matt Omasta combine clear, accessible writing and analytic insight to show that analysis, in its broadest sense, is a process undertaken throughout the entire research experience. This work provides a thought-provoking account of how medical treatments can be tested with unbiased or 'fair' trials and explains how patients can work with doctors to achieve this vital goal. It spans the gamut of therapy from mastectomy to thalidomide and explores a vast range of case studies. 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. 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. This graduate level nursing research textbook continues the expansion of coverage on qualitative research, including important issues for specific qualitative traditions such as grounded theory, phenomenology and ethnography. Developing solid evidence for practice will be emphasized throughout the text, and important evaluative concepts like reliability, validity, and trustworthiness will be introduced. Other new features include stronger international content (with an emphasis on Canadian and Australian research), inclusion of “tips” in boxes located in appropriate places throughout the chapters, and the use of summary bullet points. This edition will now offer a free Connection Website, connection.LWW.com/go/polit. The chapters in the first section focus on individual presenting symtoms and/or findings and describe the best approach to sort through the differential diagnosis, determine whether the problem is hematologic or oncologic, and to rapidly ascertain the definitive diagnosis. The chapters in the second section each describe a specific disease with a focus on evaluation and management. 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. Clinical trials have become essential research tools for evaluating the benefits and risks of new interventions for the treatment and prevention of diseases, from cardiovascular disease to cancer to AIDS. Based on the authors’ collective experiences in this field, Introduction to Statistical Methods for Clinical Trials presents various statistical topics relevant to the design, monitoring, and analysis of a clinical trial. After reviewing the history, ethics, protocol, and regulatory issues of clinical trials, the book provides guidelines for formulating primary and secondary questions and translating clinical questions into statistical ones. It examines designs used in clinical trials, presents methods for determining sample size, and introduces constrained randomization procedures. The authors also discuss how various types of data must be collected to answer key questions in a trial. In addition, they explore common analysis methods, describe statistical methods that determine what an emerging trend represents, and present issues that arise in the analysis of data. The book concludes with suggestions for reporting trial results that are consistent with universal guidelines recommended by medical journals. Developed from a course taught at the University of Wisconsin for the past 25 years, this textbook provides a solid understanding of the statistical approaches used in the design, conduct, and analysis of clinical trials. Wherever you study or practise obstetrics and gynaecology, a sound knowledge of the clinical aspects will underpin your understanding of the specialty and maximise your ability to make a difference to the care of women and babies. A perfect companion to Kumar and Clark’s Clinical Medicine, this new edition continues to provide an excellent grounding and framework for handling clinical problems in obstetrics and gynaecology. Highly illustrated with clear, full-colour line drawings and colour photos. Summary boxes and tables throughout. Key-points boxes at the end of each chapter. The latest information for statistics and genetics. Forward-looking approach to obstetrics and gynaecology. History and ethics boxes throughout. Organized into three sections: Fundamentals, Gynaecology, and Pregnancy and the puerperium. New section on sexual and reproductive health New chapter on surgery to aligned with the RCOG undergrad curriculum Anaesthesia chapter totally reworked. Increased coverage of ectopic pregnancy and miscarriage. Fully revised and updated throughout. This extensively revised new edition comprehensively reviews the rise of clinical research informatics (CRI). It enables the reader to develop a thorough understanding of how CRI has developed and the evolving challenges facing the biomedical informatician in the modern clinical research environment. Emphasis is placed on the changing role of the consumer, and the need to merge clinical care delivery and research as part of a changing paradigm in global healthcare delivery. Clinical Research Informatics presents a detailed review of using informatics in the continually evolving clinical research environment. It represents a valuable textbook reference for all students and practising healthcare informaticians looking to learn and expand their understanding of this fast-moving and increasingly important discipline. 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. 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. Pharmaceutical companies, academic researchers, and government agencies such as the Food and Drug Administration and the National Institutes of Health all possess large quantities of clinical research data. If these data were shared more widely within and across sectors, the resulting research advances derived from data pooling and analysis could improve public health, enhance patient safety, and spur drug development. Data sharing can also increase public trust in clinical trials and conclusions derived from them by lending transparency to the clinical research process. Much of this information, however, is never shared. Retention of clinical research data by investigators and within organizations may represent lost opportunities in biomedical research. Despite the potential benefits that could be accrued from pooling and analysis of shared data, barriers to data sharing faced by researchers in industry include concerns about data mining, erroneous secondary analyses of data, and unwarranted litigation, as well as a desire to protect confidential commercial information. Academic partners face significant cultural barriers to sharing data and participating in longer term collaborative efforts that stem from a desire to protect intellectual autonomy and a career advancement system built on priority of publication and citation requirements. Some barriers, like the need to protect patient privacy, pre- sent challenges for both sectors. Looking ahead, there are also a number of technical challenges to be faced in analyzing potentially large and heterogeneous datasets. This public workshop focused on strategies to facilitate sharing of clinical research data in order to advance scientific knowledge and public health. While the workshop focused on sharing of data from preplanned interventional studies of human subjects, models and projects involving sharing of other clinical data types were considered to the extent that they provided lessons learned and best practices. The workshop objectives were to examine the benefits of sharing of clinical research data from all sectors and among these sectors, including, for example: benefits to the research and development enterprise and benefits to the analysis of safety and efficacy. Sharing Clinical Research Data: Workshop Summary identifies barriers and challenges to sharing clinical research data, explores strategies to address these barriers and challenges, including identifying priority actions and "low-hanging fruit" opportunities, and discusses strategies for using these potentially large datasets to facilitate scientific and public health advances. Missing Data in Clinical Studies provides a comprehensive account of the problems arising when data from clinical and related studies are incomplete, and presents the reader with approaches to effectively address them. The text provides a critique of conventional and simple methods before moving on to discuss more advanced approaches. The authors focus on practical and modeling concepts, providing an extensive set of case studies to illustrate the problems described. Provides a practical guide to the analysis of clinical trials and related studies with missing data. Examines the problems caused by missing data, enabling a complete understanding of how to overcome them. Presents conventional, simple methods to tackle these problems, before addressing more advanced approaches, including sensitivity analysis, and the MAR missingness mechanism. Illustrated throughout with real-life case studies and worked examples from clinical trials. Details the use and implementation of the necessary statistical software, primarily SAS. Missing Data in Clinical Studies has been developed through a series of courses and lectures. Its practical approach will appeal to applied statisticians and biomedical researchers, in particular those in the biopharmaceutical industry, medical and public health organisations. Graduate students of biostatistics will also find much of benefit. With the increasing emphasis on evidence-based practice, there is a need for all health and social care professionals to understand the principles of general and clinical research. In the United Kingdom and several other countries, this had led to a proliferation of advanced programs, including for those seeking doctorate degrees. In this book, the editors introduce readers to the principles and practice of clinical research. Eighteen chapters and three appendices provide guidance on the different stages of a research project, from inception to the dissemination of results. Topics include: • steps to engage in practice-based research; • ethical questions surrounding research; • sources of funding; • collecting and collating data. Contributing authors emphasize the need to critically appraise literature before carrying out a research project. They also explain the stages of a research project and share insights on where to go for more information. The book includes an index, a glossary, and charts and figures to promote learning. Discussion questions reinforce critical material. This book reviews research on Dan Shen, compiles data from clinical trials and biological experiments, and summarizes the latest research advances. It covers the medicinal herb, herbal pieces, and new proprietary drugs that contain it; it also covers simple and compound, traditional and contemporary formulas, and addresses a broad range of subjects, including: standardized cultivation; biodiversity; effective substances and their biological activities; quality control; and clinical trials. The book goes on to present the clinical trials on Dantonic, especially focusing on its therapeutic effects for coronary heart disease. It discusses compound prescriptions and compatibilities, from the herbal piece level to composition level, and describes approaches to research on modern Chinese medicine. Volume 1 describes the biology and chemistry of Dan Shen, while Volume 2 focuses on pharmacology and quality control. Volume 3 describes the clinical research on Dan Shen. Editor Xijun Yan is the President of Tianjin Tasly Group and a Member of the TCM Standardization Technical Committee. Gathering contributions from more than 100 authors working in the field of pharmaceutical and clinical research, the book presents and analyzes the available information from multiple aspects, reflects the current status of Dan Shen research, and offers an essential reference work for further research and development. This is a comprehensive major reference work for our SpringerReference program covering clinical trials. Although the core of the Work will focus on the design, analysis, and interpretation of scientific data from clinical trials, a broad spectrum of clinical trial application areas will be covered in detail. This is an important time to develop such a Work, as drug safety and efficacy emphasizes the Clinical Trials process. Because of an immense and growing international disease burden, pharmaceutical and biotechnology companies continue to develop new drugs. Clinical trials have also become extremely globalized in the past 15 years, with over 225,000 international trials ongoing at this point in time. Principles in Practice of Clinical Trials is truly an interdisciplinary that will be divided into the following areas: 1) Clinical Trials Basic Perspectives 2) Regulation and Oversight 3) Basic Trial Designs 4) Advanced Trial Designs 5) Analysis 6) Trial Publication 7) Topics Related Specific Populations and Legal Aspects of Clinical Trials The Work is designed to be comprised of 175 chapters and approximately 2500 pages. The Work will be oriented like many of our SpringerReference Handbooks, presenting detailed and comprehensive expository chapters on broad subjects. The Editors are major figures in the field of clinical trials, and both have written textbooks on the topic. There will also be a slate of 7-8 renowned associate editors that will edit individual sections of the Reference. Data sharing can accelerate new discoveries by avoiding duplicative trials, stimulating new ideas for research, and enabling the maximal scientific knowledge and benefits to be gained from the efforts of clinical trial participants and investigators. At the same time, sharing clinical trial data presents risks, burdens, and challenges. These include the need to protect the privacy and honor the consent of clinical trial participants; safeguard the legitimate economic interests of sponsors; and guard against invalid secondary analyses, which could undermine trust in clinical trials or otherwise harm public health. Sharing Clinical Trial Data presents activities and strategies for the responsible sharing of clinical trial data. With the goal of increasing scientific knowledge to lead to better therapies for patients, this book identifies guiding principles and makes recommendations to maximize the benefits and minimize risks. This report offers guidance on the types of clinical trial data available at different points in the process, the points in the process at which each type of data should be shared, methods for sharing data, what groups should have access to data, and future knowledge and infrastructure needs. Responsible sharing of clinical trial data will allow other investigators to replicate published findings and carry out additional analyses, strengthen the evidence base for regulatory and clinical decisions, and increase the scientific knowledge gained from investments by the funders of clinical trials. The recommendations of Sharing Clinical Trial Data will be useful both now and well into the future as improved sharing of data leads to a stronger evidence base for treatment. This book will be of interest to stakeholders across the spectrum of research--from funders, to researchers, to journals, to physicians, and ultimately, to patients. This book presents state-of-the-art information on both the scientific and clinical aspects of the Millon Clinical Multiaxial Inventory, a test that uniquely assesses both personality pathology and psychopathology. The book presents original contributions from major researchers/clinicians who have published seminal papers on the MCMI and who are recognized authorities in their specific areas. Clinical examples of the MCMI with a variety of

clinical populations are provided, and many chapters summarize the research in that area as well as present clinical illustrations of the MCMI with actual cases. The book provides the reader with the most accurate information on the MCMI -- a test that has made exciting advances in the assessment of personality and psychopathology. The scientific and clinical status of this instrument is presented with a variety of clinical populations, including major psychiatric disorders, depression, substance abuse, anxiety disorders, eating and stress disorders, etc. Recent applications and advances in special areas, such as the instrument's use with medical populations and non-clinical populations, are also presented. As many medical and healthcare researchers have a love-hate relationship with statistics, the second edition of this practical reference book may make all the difference. Using practical examples, mainly from the authors' own research, the book explains how to make sense of statistics, turn statistical computer output into coherent information, and help decide which pieces of information to report and how to present them. The book takes you through all the stages of the research process, from the initial research proposal, through ethical approval and data analysis, to reporting on and publishing the findings. Helpful tips and information boxes, offer clear guidance throughout, including easily followed instructions on how to: -develop a quantitative research proposal for ethical/institutional approval or research funding -write up the statistical aspects of a paper for publication -choose and perform simple and more advanced statistical analyses -describe the statistical methods and present the results of an analysis. This new edition covers a wider range of statistical programs - SAS, STATA, R, and SPSS, and shows the commands needed to obtain the analyses and how to present it, whichever program you are using. Each specific example is annotated to indicate other scenarios that can be analysed using the same methods, allowing you to easily transpose the knowledge gained from the book to your own research. The principles of good presentation are also covered in detail, from translating relevant results into suitable extracts, through to randomised controlled trials, and how to present a meta-analysis. An added ingredient is the inclusion of code and datasets for all analyses shown in the book on our website (http://medical-statistics.info). Written by three experienced biostatisticians based in the UK and US, this is a step-by-step guide that will be invaluable to researchers and postgraduate students in medicine, those working in the professions allied to medicine, and statisticians in consultancy roles. 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. 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. 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. There are nearly 24,000 ophthalmologists in the United States, with 500 physicians newly entering the ophthalmology field each year and approximately half of those being women. Although women now represent approximately half of all ophthalmologists, gender disparities remain when it comes to certain subspecialties (e.g., surgical retina), leadership roles (e.g., department chairs), industry involvement (e.g., consultancy and advisory board positions), and even academic publications. There has been a recently heightened interest in female representation in this field which has manifested in several ways (e.g., conferences geared towards women in ophthalmology, non-peer-reviewed publications about women in ophthalmology, and mentorship programs specifically for women). This book is the first of its kind in procuring and disseminating information—pertaining to both career and life—in an organized, concrete, and enduring way. Women in Ophthalmology is a comprehensive collection of chapters primarily written by women in the field of ophthalmology. The book aims to guide others through milestones and challenges women may face during their careers, and shares sound insights into how to deal with unique issues both inside and outside the workplace. Topics that are widely applicable to all who work in ophthalmology are included, such as finding mentors, collaborating within industry, handling work-life balance, and seeking out leadership opportunities. Each chapter combines personal anecdotes with knowledge from leaders in the field which both men and women will find highly valuable. For more than 30 years, Designing Clinical Research has set the standard as the most practical, authoritative guide for physicians, nurses, pharmacists, and other practitioners involved in all forms of clinical and public health research. Using a reader-friendly writing style, Drs. Warren S. Browner, Thomas B. Newman, Steven R. Cummings, Deborah G. Grady, Alison J. Huang, Alka M. Kanaya, and Mark J. Pletcher, all of the University of California, San Francisco, provide up-to-date, commonsense approaches to the challenging judgments involved in designing, funding, and implementing a study. This state-of-the-art fifth edition features new figures, tables, and design, as well as new editors, new content, and extensively updated references to keep you current. An ideal health care system relies on efficiently generating timely, accurate evidence to deliver on its promise of diminishing the divide between clinical practice and research. There are growing indications, however, that the current health care system and the clinical research that guides medical decisions in the United States falls far short of this vision. The process of generating medical evidence through clinical trials in the United States is expensive and lengthy, includes a number of regulatory hurdles, and is based on a limited infrastructure. The link between clinical research and medical progress is also frequently misunderstood or unsupported by both patients and providers. The focus of clinical research changes as diseases emerge and new treatments create cures for old conditions. As diseases evolve, the ultimate goal remains to speed new and improved medical treatments to patients throughout the world. To keep pace with rapidly changing health care demands, clinical research resources need to be organized and on hand to address the numerous health care questions that continually emerge. Improving the overall capacity of the clinical research enterprise will depend on ensuring that there is an adequate infrastructure in place to support the investigators who conduct research, the patients with real diseases who volunteer to participate in experimental research, and the institutions that organize and carry out the trials. To address these issues and better understand the current state of clinical research in the United States, the Institute of Medicine's (IOM) Forum on Drug Discovery, Development, and Translation held a 2-day workshop entitled Transforming Clinical Research in the United States. The workshop, summarized in this volume, laid the foundation for a broader initiative of the Forum addressing different aspects of clinical research. Future Forum plans include further examining regulatory, administrative, and structural barriers to the effective conduct of clinical research; developing a vision for a stable, continuously funded clinical research infrastructure in the United States; and considering strategies and collaborative activities to facilitate more robust public engagement in the clinical research enterprise. 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. 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. NATIONAL BOOK CRITICS CIRCLE AWARD WINNER • The first full history of Black America's shocking mistreatment as unwilling and unwitting experimental subjects at the hands of the medical establishment. No one concerned with issues of public health and racial justice can afford not to read this masterful book. "[Washington] has unearthed a shocking amount of information and shaped it into a riveting, carefully documented book." —New York Times From the era of slavery to the present day, starting with the earliest encounters between Black Americans and Western medical researchers and the racist pseudoscience that resulted, Medical Apartheid details the ways both slaves and freedmen were used in hospitals for experiments conducted without their knowledge—a tradition that continues today within some black populations. It reveals how Blacks have historically been prey to grave-robbing as well as unauthorized autopsies and dissections. Moving into the twentieth century, it shows how the pseudoscience of eugenics and social Darwinism was used to justify experimental exploitation and shoddy medical treatment of Blacks. Shocking new details about the government's notorious Tuskegee experiment are revealed, as are similar, less-well-known medical atrocities conducted by the government, the armed forces, prisons, and private institutions. The product of years of prodigious research into medical journals and experimental reports long undisturbed, Medical Apartheid reveals the hidden underbelly of scientific research and makes possible, for the first time, an understanding of the roots of the African American health deficit. At last, it provides the fullest possible context for comprehending the behavioral fallout that has caused Black Americans to view researchers—and indeed the whole medical establishment—with such deep distrust. 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

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