

Principles of Research Methodology A Guide for Clinical Investigators

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Written and edited by Dr. Phyllis Supino and Jeffrey Borer, this book on research methodology draws from the common experiences of those involved in training early-career researchers. Dr. Supino and Borer's book represents the collaboration of an accomplished educator and scholar with expertise in research methodology. The institute, of which Dr. Borer is director, is now located at the State University of New York Downstate Medical Center Working as part of a research institute housed in a medical school. Dr. Borer soon discovered that many of the students in his program had no formal research training and little knowledge of research methodology. That is why he had the idea to write a book. The book includes in-depth chapters that not only generate research questions, but also provide important information on how to create better research, including researching a variety of databases, research grants, and documenting. On the history of the application of ethics to medical research. There also is a valuable chapter on statistical considerations and a fascinating discussion on the origins and elements of hypothesis generation. The book spans the entire research process, beginning with the conception of the research problem to publication of findings. This book consists of 13 chapters. A brief summary of the contents of each chapter. Chapter 1 describes the general characteristics of research and differentiates among various types of research; it also summarizes the steps typically utilized in the hypothesis-testing (hypothetico-deductive) method and underscores the importance of proper planning. Chapter 2 reviews the origins of clinical research problems and the types of questions that are commonly asked in clinical investigations; it also identifies the characteristics of well-conceived research problems and explains the role of the literature search in research problem development. Chapter 3 introduces the reader to various modes of logical inference utilized for hypothesis generation, describes the characteristics of well-designed research hypotheses, distinguishes among various types of hypotheses, and provides guidelines for constructing them. Chapter 4 takes the reader through classic epidemiological (observational) methods, including cohort, case-control, and cross-sectional designs, and describes their respective advantages and limitations. Chapter 5 discusses the meaning of internal and external validity in the context of studies that aim to examine the effects of purposively applied interventions, identifies the most important sources of bias in these types of studies, and presents a

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Physician Investigator Handbook Deborah Rosenbaum, Fred Smith, 2002-01-01 A comprehensive guide for physicians conducting clinical research this second edition addresses a broader research perspective It includes information on the implications of the ICH Guidelines current FDA regulations and an Internet address directory Everything the clinical trial manager planner monitor and investigator need to know about the design establishment monitoring and close out of a trial is in this book The chapters address the elements of clinical research professional interactions FDA regulations and good clinical practices guidelines investigational agent management designing a study and protocol development conducting the study and more

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is provided online Topics include An overview of the clinical development process A review of regulatory requirements How to set up and manage a research center How to effectively and efficiently conduct clinical trials and How to identify and secure clinical grant opportunities

Oncology Clinical Trials William Kevin Kelly,Susan Halabi,2018-03-28 The second edition of Oncology Clinical Trials has been thoroughly revised and updated and now contains the latest designs and methods of conducting and analyzing cancer clinical trials in the era of precision medicine with biologic agents including trials investigating the safety and efficacy of targeted therapies immunotherapies and combination therapies as well as novel radiation therapy modalities Now divided into six sections this revamped book provides the necessary background and expert guidance from the principles governing oncology clinical trials to the innovative statistical design methods permeating the field from conducting trials in a safe and effective manner analyzing and interpreting the data to a forward looking assessment and discussion of regulatory issues impacting domestic international and global clinical trials Considered by many as the gold standard reference on oncology clinical trials in the field the second edition continues to provide examples of real life flaws and real world examples for how to successfully design conduct and analyze quality clinical trials and interpret them With chapters written by oncologists researchers biostatisticians clinical research administrators and industry and FDA representatives this volume provides a comprehensive guide in the design conduct monitoring analysis and reporting of clinical trials in oncology

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Comprehensively covers all regulatory aspects in the pursuit of global oncology trials Digital access to the ebook included

Dictionary of Pharmaceutical Medicine Gerhard Nahler,2013-04-12 This dictionary includes various terms typically used in pharmaceutical medicine The 3rd edition underlines the increasing importance of this science and the changing regulatory environment especially focusing on the research and development of new therapies as well as on conducting clinical trials marketing authorizations for new medicinal products and safety aspects including pharmacovigilance The number of keywords has been considerably enlarged and is accompanied by an up to date list of the most important websites Similar to the previous editions this new book explains roughly 1 000 abbreviations most commonly used in pharmaceutical medicine This volume will be a valuable tool for professionals working in the pharmaceutical industry medical and preclinical research regulatory affairs marketing and marketing authorization of pharmaceuticals

Concise Biostatistical Principles and Concepts, 2nd Edition Laurens Holmes, Jr,2025-03-18 Concise Biostatistical Principles and Concepts Statistical Reality in Evidence Discovery Clinical medicine or surgery continues to make advances through evidence that is judged to be

objectively drawn from the care of individual patients The natural observation of individuals remains the basis for our researchable questions formulation and the subsequent hypothesis testing Evidence based medicine or surgery depends on how critical we are in evaluating evidence in order to inform our practice These evaluations no matter how objective are never absolute but probabilistic as we will never know with absolute certainty how to treat future patients who were not a part of our study Despite the obstacles facing us today in an attempt to provide an objective evaluation of our patients since all our decisions are based on a judgment of some evidence we have progressed from expert opinion to the body of evidence from randomized controlled clinical trials as well as cohort investigations prospective and retrospective The conduct of clinical trials though termed the gold standard which yields more reliable and valid evidence from the data relative to non experimental or observational designs depends on how well it is designed and conducted prior to outcomes data collection analysis results interpretation and dissemination The designs and the techniques used to draw statistical inferences are often beyond the average clinician s understanding A text that brings hypothesis formulation analysis and how to interpret the results of the findings is long overdue and highly anticipated Statistical modeling which is fundamentally a journey from sample to the application of findings is essential to evidence discovery The four past decades have experienced modern advances in statistical modeling and evidence discovery in biomedical clinical and population based research With these advances come the challenges in accurate model stipulation and application of models in scientific evidence discovery While the application of novel statistical techniques to our data is necessary and fundamental to research the selection of a sample and sampling method that reflects the representativeness of that sample to the targeted population is even more important Since one of the rationale behind research conduct is to generate new knowledge and apply it to improve life situations including the improvement of patient and population health sampling sample size and power estimations remain the basis for such inference With the essential relevance of sample and sampling technique to how we come to make sense of data the design of the study transcends statistical technique since no statistical tool no matter how sophisticated can correct the errors of sampling This text is written to highlight the importance of appropriate design prior to analysis by placing emphasis on subject selection and probability sample randomization process when applicable prior to the selection of the analytic tool In addition it stresses the importance of biological and clinical significance in the interpretation of study findings The basis for statistical inference implying the quantification of random error is a random sample When studies are conducted without random samples as often encountered in clinical and biomedical research it is meaningless to report the findings with p value However in the absence of a random sample the p value can be applied to designs that utilize consecutive samples and disease registries since these samples reflect the population of interest and hence representative sample justifying inference and generalization Essential to the selection of test statistics is the understanding of the scale of the measurement of the variables especially the response outcome or dependent variable type of sample independent or correlated hypothesis and

normality assumption In terms of the selection of statistical tests this text is based on the scale of measurement binary type of sample single independent and relationship linear For example if the scale of measurement of the outcome variable is binary repeated measure and normality is not assumed the repeated measure logistic regression model remains a feasible model for evidence discovery in using the independent variables to predict the repeated outcome This book presents a simplified approach to evidence discovery by recommending the graphic illustration of data and normality test for continuous ratio interval scale data prior to statistical test selection Unlike current text in biostatistics the approach taken to present these materials is very simple First this text uses applied statistics by illustrating what when where and why a test is appropriate Where a text violates the normality assumption readers are presented with a non parametric alternative The rationale for the test is explained with a limited mathematical formula and is intended in order to stress the applied nature of biostatistics Attempts have been made in this book to present the most commonly used statistical model in biomedical or clinical research We believe since no book is complete to have covered the basics that will facilitate the understanding of scientific evidence discovery We hope this book remains a useful guide which is our intention in bridging the gap between theoretical statistical models and reality in the statistical modeling of biomedical and clinical research data As researchers we all make mistakes and we believe we have learned from our mistakes during the past three decades hence the need to examine flaws and apply reality in the statistical modeling of biomedical and research data We hope this text results in increased reliability in the conduct analysis

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