

GUIDE TO CLINICAL TRIALS

BERT SPILKER



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National Library of Medicine Current Catalog National Library of Medicine (U.S.), *A Clinical Trials Manual From The Duke Clinical Research Institute* Margaret Liu,Kate Davis,2011-08-24 The publication of the second edition of this manual comes at an important juncture in the history of clinical research As advances in information technology make it possible to link individuals and groups in diverse locations in jointly seeking the answers to pressing global health problems it is critically important to remain vigilant about moral and ethical safeguards for every patient enrolled in a trial Those who study this manual will be well aware of how to ensure patient safety along with fiscal responsibility trial efficiency and research integrity Robert Harrington Professor of Medicine Director Duke Clinical Research Institute Durham North Carolina USA The Duke Clinical Research Institute DCRI is one of the world s leading academic clinical research organizations its mission is to develop and share knowledge that improves the care of patients around the world through innovative clinical research This concise handbook provides a practical nuts and bolts approach to the process of conducting clinical trials identifying methods and techniques that can be replicated at other institutions and medical practices Designed for investigators research coordinators CRO personnel students and others who have a desire to learn about clinical trials this manual begins with an overview of the historical framework of clinical research and leads the reader through a discussion of safety concerns and resulting regulations Topics include Good Clinical Practice informed consent management of subject safety and data as well as monitoring and reporting adverse events Updated to reflect recent regulatory and clinical developments the manual reviews the conduct of clinical trials research in an increasingly global context This new edition has been further expanded to include In depth information on conducting clinical trials of medical devices and biologics The role and responsibilities of Institutional Review Boards and Recent developments regarding subject privacy concerns and regulations Ethical documents such as the Belmont Report and the Declaration of Helsinki are reviewed in relation to all aspects of clinical research with a discussion of how researchers should apply the principles outlined in these important documents This graphically appealing and eminently readable manual also provides sample forms and worksheets to facilitate data management and regulatory record retention these can be modified and adapted for use at investigative sites

Guide to Clinical Studies and Developing Protocols Bert Spilker,1984 *Institutional Review Boards, a System in Jeopardy* United States. Congress. House. Committee on Government Reform and Oversight. Subcommittee on Human Resources,1999 Contemporary Issues in Bioethics Peter A. Clark,2012-03-07 The main strength of this book is the international exchange of ideas that will not only highlight many of these crucial bioethical issues but will strengthen the discipline of bioethics both nationally and globally A critical exchange of ideas allows everyone to learn and benefit from the

insights gained through others experiences Analyzing and understanding real medical ethical issues and cases and how they are resolved is the basis of education in bioethics for those who will have to make these decisions in the future The more we examine analyze and debate these bioethical issues and cases the more knowledge will be gained and hopefully we will all gain more practical wisdom

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Pediatric Inflammatory Bowel Disease Petar Mamula,Jonathan E. Markowitz,Robert N. Baldassano,2007-11-24 Pediatric Inflammatory Bowel Diseases IBD are the most common and most significant chronic disorders in Pediatric Gastroenterology The onset of Crohn disease and ulcerative colitis in the first two decades of life presents a number of diagnostic and therapeutic challenges that are unique to pediatric patients Although the studies available for pediatric diagnosis have improved dramatically in the past three decades the improvement in technology alone cannot account for the increased frequency of IBD recognized in early childhood While therapy for older patients has improved dramatically with the use of immunomodulators and the development of exciting biologic strategies rarely if ever have comprehensive studies of the pharmacokinetics safety and efficacy of any of the IBD medications been performed in pediatric patients A number of excellent medications are not

available in liquid preparations that can be swallowed by children and others such as timed release formulations are developed for delivery to an adult gastrointestinal tract It is unfortunate that the care we provide to children is often an extrapolation of what is known about and available for adults with IBD Pediatric patients with IBD face a number of unique challenges The onset of disease before puberty can be devastating Growth failure is a particularly difficult problem with potentially permanent consequences Much of the pediatric specific research has focused on the role of nutritional therapy to treat growth failure and induce remission *Quality of Life Assessments in Clinical Trials* Bert Spilker,1990

Presentation of Clinical Data Bert Spilker,John Schoenfelder,1990 The CRC's Guide to Coordinating Clinical Research Karen E. Woodin,2004 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 **Principles and Practice of Pharmaceutical Medicine** Andrew J. Fletcher,Lionel D. Edwards,Anthony W. Fox,Peter D. Stonier,2003-01-31 Principles and Practice of Pharmaceutical Medicine begins with a detailed overview of its origins and goes on to examine current career opportunities education and training Encompassing the entire spectrum of pharmaceutical medicine it also discusses international drug development and registration including animal toxicology and human volunteers pharmacoeconomics and statistics medical services legal and ethical issues and business aspects It is the most up to date guide to drug development and marketing and the only book with an international outlook The authors are all experts in their field and include an assessment of the current status of their specialities This book provides an insight into how things may develop in the future It is designed to be a guide for those who are actually practicing pharmaceutical medicine **Data Collection Forms in Clinical Trials** Bert Spilker,1991 *The Role of Complementary and Alternative Medicine* Daniel Callahan,2001-12-18 At the center of the debate over complementary and alternative medicine from acupuncture and chiropractic treatments to homeopathy and nutritional supplements is how to scientifically measure the effectiveness of a particular treatment Fourteen scholars from the fields of medicine philosophy sociology and cultural and folklore studies examine that debate and the clash between growing public support and the often hostile stance of clinicians and medical researchers Proponents and critics have different methodologies and standards of evidence raising the question of how much pluralism is acceptable in a medical context particularly in light of differing worldviews and the struggle to define medicine in the modern world The contributors address both the methodological problems of assessment and the conflicting cultural perspectives at work in a patient s choice of treatment Sympathetic to CAM the contributors nonetheless offer careful critiques of its claims and suggest a variety of ways it can be taken seriously yet subject to careful scrutiny Journal of Pediatric Gastroenterology and Nutrition ,1993 **SAMT** ,1992-07 Clinical Pharmacy ,1992

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