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This revised edition of a bestseller provides a logical, step-by-step guide to testing new drugs and treatment modalities in compliance with the latest FDA regulations. With current forms, ICH GCP information, FDA regulations, and other references, it shows readers how to manage a clinical research study effectively and efficiently.

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Clinical Research Coordinator Handbook PDF Free Download E-BOOK DESCRIPTION In this fully revised and expanded fourth edition of the essential reference for clinical research coordinators, Deborrah Norris provides expanded coverage of CRC duties and

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regulatory requirements, including new sections on investigator responsibilities, data clarification, and adverse event reporting.

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It is the responsibility of the research monitor to manage numerous trials at various centers, as well as keep everyone on schedule. In this completely revised edition, topics covered include designing case report forms, interacting with clinicians and other health professionals, and discovering employment options and career paths within the industry. Complete with checklists, tables, charts, references, and a glossary, this book provides you with all of the information you need to perform effectively. Expanded to address a broader research perspective, this edition also includes more

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information on the implications of the ICH Guidelines and current FDA regulations and references.

In this revised third edition of the essential reference for clinical research coordinators (CRCs), Deborah 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

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and contact information, conversion charts and tables, a glossary, and more.

This revised edition of a bestseller provides a logical, step-by-step guide to testing new drugs and treatment modalities in compliance with the latest FDA regulations. With current forms, ICH GCP information, FDA regulations, and other references, it shows readers how to manage a clinical research study effectively and efficiently.

"The publication of the second edition of this manual comes at an important juncture in

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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

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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

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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

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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

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record retention; these can be modified and adapted for use at investigative sites.

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.

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This book is divided into 25 chapters covering more than 300 topics. This book will serve as a training guide to make your routine tasks more efficient, compliant and easy. After reading this book, Clinical Research Coordinators, clinical research personnel and aspirants would get:

- # Step by step in-depth training on roles and responsibilities of a clinical research coordinator before, during and after the completion of a clinical trial.
- # Discussion on day-to-day challenges and their solutions.
- # Training through real-time examples and ready-made checklists to conduct each

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guidelines. # Tips on effective communication
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Condensing the most important topics in all
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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

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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 Operations Monitoring Dynamics and Typical Monitoring Visits CRO Activities Sponsor Level Dynamics Industry Vendors Common Career Opportunities and Employment Roadmaps

Clinical Research Manual: Practical Tools and

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Templates for Managing Clinical Research is the "must-have" book for anyone working in the day-to-day operations of a research study or clinical trial. Filled with tools, techniques, and templates, this manual offers clinical researchers, principal investigators, and research coordinators the foundation they need to successfully organize complex trials.

Designing Clinical Research sets the standard for providing a practical guide to planning, tabulating, formulating, and implementing clinical research, with an easy-to-read,

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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.

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This book is a must-read for students and professionals for a broad understanding of the entire process of clinical trial operation. In the second edition released in December 2017, we have added several new topics of interest taking the total count to 112. At the moment, a clinical trial is the most relevant method at our disposal to explore and establish safety/efficacy of a new medicine. It is the fundamental basis of clinical development programs of healthcare products. Clinical research has opened up several new career choices. Graduates in

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medicine, pharmacy, and other life sciences now have the option to work as investigators, scientists, project managers, data managers, monitors, study coordinators, regulatory affairs managers, and so on. Many of these positions have specialized and focused responsibilities in the industry setting. Considering the highly complex environment of clinical research, a broad overview is indispensable for effective collaboration. This book has been written for life science graduates aspiring to work in clinical research industry or clinical research professionals without considerable experience

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in trial operation. It would also be useful for professionals with focused responsibilities to broaden understanding of the entire gamut of trial operation. As fundamental approach is independent of nature of the investigational product (e.g. drug, device, vaccine or diagnostic agent), we are hopeful of its wider usefulness to the entire healthcare industry. The objective is to provide a broad outline of key activities, principles, roles, and responsibilities without getting into procedural details. Most organizations involved in clinical research have defined processes and procedures to

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carry out specific responsibilities relevant to their business. Hence, the discussion is purposefully limited to an overview to keep it concise yet informative. Discussion in each topic covers the background, operational overview, and usual challenges. Frequently used terminology has been introduced in the context of specific topics to induce familiarity. The book has been organized into several topics from the perspective of a project manager driving an entire trial. Organization of topics is according to the flow of trial operation from conception to the end. At the outset, the context of

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different trials according to phases of drug development has been introduced. Subsequent topics are on planning, setup, execution, and closeout in a sequential manner. Towards the end, the topics are on few general aspects of trial operation. This book has been written based on our practical experience, as well as regulatory guidance and other freely accessible literature. Good clinical practice (GCP) lays down the fundamental guiding principles for trial operation. Familiarity with any GCP guidance is highly recommended for the best outcome from this book.

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