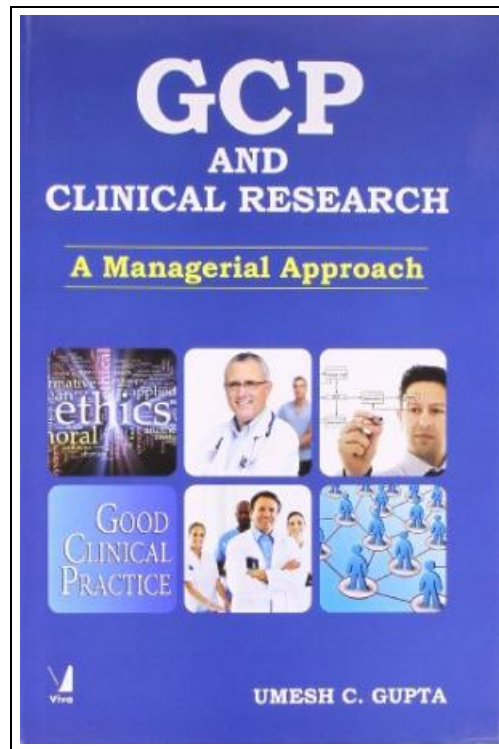


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Viva Books, 2011. Hardcover. Book Condition: New. First edition. Clinical research in India has grown at an unprecedented rate in the last few years opening many new opportunities. At the same time, especially being a part of global clinical trials, it has put serious challenges for the compliance of trial conduct and validity and integrity of clinical trial data. Towards contributing to the corporate goals of established and emerging CROs and pharmaceutical firms, regarding research, innovation, profitability, and long-term sustainable growth, clinical research domain has become highly regulated and complicated requiring sound knowledge, project management skills and aspirations to achieve compliance with domestic and international regulations as well as towards achieving competitive, quality, compliance, cost and time benefits. This book, an a next-generation book, with plenty of tables, figures, and flow charts has been written with a purpose to satisfy the above unmet need and provides a quality pathway for conducting clinical trials. Contents: List of Abbreviations ? Chapter 1: Introduction to Clinical Research ? Clinical Trial: Definition ? Significance of Clinical Trials ? Sponsor and Site for Clinical Trial ? Regulations Governing Clinical Trials ? Ethics Committee in Clinical Trials ? Risks Involved in Clinical Trials ? Benefits of Clinical Trials ? Participants in Clinical Trials ? Conducting a Clinical Trial ? After the Completion of a Clinical Trial ? Types of Clinical Trials ? New Drug Development Process ? Clinical Development of a New Drug ? Phase I Trials (Human Pharmacology Trials or First in Human Studies) ? Types of Phase I: Trials ? Single Ascending Dose (SAD) Studies ? Multiple Ascending Dose (MAD) Studies ? Food Effect ? Phase II: Trials (Therapeutic Exploratory Trials or Proof of Concept) ? Phase III: Trials (Therapeutic Confirmatory Trials) ? Phase IV: Trials (Post-Marketing Trials) ? Clinical Trials in India ?...



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