

A Comprehensive and Practical Guide in Clinical Trials

The Comprehensive and Practical Guide in Clinical Trials, Second Edition offers a thorough update to the foundational handbook on clinical trial conduct. It reflects the evolving landscape of clinical research since 2017, incorporating new regulatory guidelines, innovations in device trials, and the shift to electronic data capture and management. This resource addresses the needs of clinical trial staff by detailing processes essential to successful trial execution. Covering all aspects of clinical research, the book includes chapters on trial phases, site selection, regulatory requirements, contracts, protocol development, informed consent, and data management. New chapters focus on project management, electronic source documents, and pharmacy operations. Each chapter integrates practical tools such as checklists, templates, and case studies to facilitate understanding and application. This handbook uniquely supports the entire clinical trial team—including investigators, coordinators, pharmacists, data managers, and regulatory personnel—by clarifying roles and responsibilities and illustrating how their tasks interconnect. Its accessible style and comprehensive scope make it an indispensable guide for planning, conducting, and closing clinical trials effectively and in compliance with international standards.

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