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Nota di contenuto	DESIGN, EXECUTION, AND MANAGEMENT OF MEDICAL DEVICE CLINICAL TRIALS; CONTENTS; List of Abbreviations; Preface; Acknowledgments; 1 An Overview of Clinical Study Tasks and Activities; Key Clinical Study Tasks and Activities; Discussion of Key Tasks and Activities; Management of Key Clinical Tasks and Activities; Example of the Spread Sheet for Managing Clinical Study Activities; The Clinical Research Team 2 Development of Clinical Protocols, Case Report Forms, Clinical Standard Operating Procedures, Informed Consent Form, Study Regulatory Binder, Study Research Agreement, and Other Clinical Materials Clinical Protocol; Case Report Forms (CRFs); Example of the Case Report Form Template; Informed Consent Form (ICF); Instructions for Use of Device; Study Regulatory Binder; Study Research Agreement; Research Agreement Template; Research Contract Challenges; Clinical Forms and Certificates; Clinical Standard Operating Procedures (SOPs) 3 Qualification/Selection of Study Investigators and Study Monitoring Visits Qualification and Selection of Investigators; Monitoring Visits; Monitoring Reports; Interim Monitoring Visit Report Template; 4 Adverse Events Definitions and Reporting Procedures; Adverse Event Definitions; Policies, Regulations, and Guidelines Regarding Adverse

Event Reporting; Adverse Event Reporting Pathway; Terms for Causality Assessment; GAPS/Challenges in Adverse Event Reporting; Adverse Event Reporting Time Periods (21 CFR 803); Differences between the United States and Europe in Reporting Adverse Events
Serious Adverse Event Narratives Classification of Adverse Events; Special Requirement for Reporting Certain Adverse Events; Case Example; Mandatory Device Reporting for FDA-Approved Devices; 5 Statistical Analysis Plan (SAP) and Biostatistics in Clinical Research; Statistical Analysis Plan (SAP); Selection of Study Endpoints; Biostatistics in Clinical Research; 6 Final Clinical Study Report; Final Clinical Report's Outline; Discussion of Sections in the Final Clinical Report; 7 Medical Device Regulations, Combination Product, Study Committees, and FDA-Sponsor Meetings
Medical Device Regulations Combination Products; Study Committees; FDA-Sponsor Meetings; Registration of Clinical Trials; Implementation of the HIPAA Privacy Rule in Clinical Research; Institutional Review Boards (IRB); FDA's Oversight of Clinical Trials (Bioresearch Monitoring); Code of Federal Regulations of Medical Devices; 8 Design Issues in Medical Devices Studies; Design of the Clinical Trial; Assumptions and Parameters of Clinical Trial Design; Clinical Trials' Design Issues and Data Analysis Issues; Use of Historic Controls as the Control Group in IDE Studies
Summary of Recommendations When Using Historic Controls

Sommario/riassunto

An essential introduction to conducting the various stages of medical device clinical trials Clinical research continues to be one of the most vital components of pharmaceutical, biostatistical, and medical studies. Design, Execution, and Management of Medical Device Clinical Trials provides a uniform methodology for conducting and managing clinical trials. Written in a style that is accessible to readers from diverse educational and professional backgrounds, this book provides an in-depth and broad overview for successfully performing clinical tasks and activities. Throughout the book,