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Autore	Abdel-aleem Salah
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Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	The Design and Management of Medical Device Clinical Trials: Strategies and Challenges; Contents; List of Abbreviations; Preface; Acknowledgments; 1. Challenges to the Design of Clinical Study; Development of Clinical SOPs; Selection of Study Patients, Investigators, and Study Sites; Definition of Enrolled Subjects in a Clinical Study; Definition of the Investigational Device System; Research Contract Challenges; Review of Literature; Challenges to the Design of the Study Protocol, Statistical Analysis Plan (SAP), and Selection of Study Endpoints; Masking or Blinding Primary and Secondary OutcomesSelection of Study Endpoints; Differences between the Primary Endpoint in FDA and CE Mark Studies; SAP and Study Endpoints; Components of the SAP for Clinical Trials; Roles and Responsibilities of the Clinical Personnel in Completing the Study Protocol; Changing the Primary Outcome during the Conduct of the Study; Definition of Primary and Secondary Endpoints; Combined ""Composite"" Endpoints; Surrogate Endpoints; Reducing the Study's Sample Size; Statistical Terms to Define Endpoint Measurements;

Reporting Results of Clinical Trials

Superiority and Equivalence TrialsSubgroup Analysis; Challenges to ICF; Risk/Benefit Analysis; 2. Challenges to Managing the Study; Enhancing Patient Enrollment by Relaxation of Study Criteria; Compliance with the Study Protocol; Challenges Associated with Data Accuracy and Completeness; Data Analysis; Data Integrity; Criteria for Using Meta-Analysis Studies; Who Should have Access to Clinical Trial Records; Managing Study Data and Quality Assurance; Missing Data Analysis; Examination of Data across Study Sites; Challenges to Adverse Event Reporting; Adverse Event Coding Systems

Protocol Deviation ReportAdverse Event Reporting in Final Study Clinical Report; Difference between the US and EU Definitions and Reporting of Adverse Events; Adverse Event Reporting Challenges; Minimization of Bias in Clinical Trials; 3. Selection of Historic Controls; Types of Control Group in Medical Device Clinical Trials; Purpose of Control Group; Use of Placebo Control; Advantages of Randomized Control Clinical Trials; Disadvantages of Randomized Control Clinical Trials; Commonly Used Pivotal Designs; Definition of Historic Control; Objective Performance Criteria (OPC)

Examples of Clinical Studies with Historic ControlsLACI Clinical Study; Left Ventricular Assist Devices; Summary of Clinical Studies; Summary of Recommendations for Historic Control; 4. Fraud and Misconduct in Clinical Trials; Fraud and Misconduct in Clinical Trials; Warning Signs of Fraud; Tips for Detecting Serious Misconduct; False Claims Act; Fraud Prevention; Policy on Handling Complaints of Misconduct; Reporting Research Misconduct; Bioresearch Monitoring Information System (BMIS); 5. Challenges to the Regulation of Medical Device; Determination of 510(K) Devices

510(K) ""Substantial Equivalence Decision Making Process""

Sommario/riassunto

Clinical trials tasks and activities are widely diverse and require certain skill sets to both plan and execute. This book provides professionals in the field of clinical research with valuable information on the challenging issues of the design, execution, and management of clinical trials, and how to resolve these issues effectively. It discusses key obstacles such as challenges to patient recruitment, investigator and study site selection, and dealing with compliance issues. Through practical examples, professionals working with medical device clinical trials will discover the appropriate s