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Autore	Martini, Giovanni Battista <1706-1784>
Titolo	Â2: ÂEsemplare o sia Saggio fondamentale pratico di contrappunto fugato dedicato all'illustrissimo, e reverendissimo monsignore Gennaro Adelelmo Pignatelli arcivescovo di Bari da F. Giambattista Martini minor conventuale accademico dell' Instituto delle Scienze, e filarm. : Parte Seconda
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Autore	Peace Karl E. <1941->
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Altri autori (Persone)	ChenDing-Geng
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Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Front cover; Contents; Preface; Chapter 1: Overview of Clinical Trial Methodology; Chapter 2: Overview of the Drug Development Process and Regulation of Clinical Trials; Chapter 3: Ethical Considerations in the Design and Conduct of Clinical Trials; Chapter 4: Sample Size Considerations in Clinical Trials Pre-Market Approval; Chapter 5: Sequential, Group Sequential, Stochastic Curtailment, and Adaptive Design Procedures in Clinical Trials; Chapter 6: Biostatistical Aspects of the Protocol; Chapter 7: The Statistical Analysis Plan; Chapter 8: Pooling of Data from Multicenter Clinical Trials; Chapter 9: Validity of Statistical Inference; Chapter 10: Bioequivalence Clinical Trials; Chapter 11: Dose and Frequency Determination from Phase II Clinical Trials in Stress Test-Induced Angina; Chapter 12: Confirmation of Clinically Optimal Dosing in the Treatment of Duodenal Ulcers: A Phase III Dose Comparison Trial; Chapter 13: Pivotal Proof-of-Efficacy Clinical Trials in the Prevention of NSAID-Induced Gastric Ulceration; Chapter 14: Clinical Trials in the Treatment of Alzheimer's Disease Based upon Enrichment Designs; Chapter 15: A Clinical Trial to Establish Reduction of CHD Risk; Chapter 16: Pivotal Proof-of-Efficacy Clinical Trials in the Treatment of Panic Disorder; Chapter 17: Combination Clinical Trials; Chapter 18: Monitoring Clinical Trials for Adverse Events; Index; Back cover

Now viewed as its own scientific discipline, clinical trial methodology encompasses the methods required for the protection of participants in a clinical trial and the methods necessary to provide a valid inference about the objective of the trial. Drawing from the authors courses on the subject as well as the first authors more than 30 years working in the pharmaceutical industry, Clinical Trial Methodology emphasizes the importance of statistical thinking in clinical research and presents the methodology as a key component of clinical research. From ethical issues and sample size considerations to adaptive design procedures and statistical analysis, the book first covers the methodology that spans every clinical trial regardless of the area of application. Crucial to the generic drug industry, bioequivalence clinical trials are then discussed. The authors describe a parallel bioequivalence clinical trial of six formulations incorporating group sequential procedures that permit sample size re-estimation. The final chapters incorporate real-world case studies of clinical trials from the authors own experiences. These examples include a landmark Phase III clinical trial involving the treatment of duodenal ulcers and Phase III clinical trials that contributed to the first drug approved for the treatment of Alzheimers disease. Aided by the U.S. FDA, the U.S. National Institutes of Health, the pharmaceutical industry, and academia, the area of clinical trial methodology has evolved over the last six decades into a scientific discipline. This guide explores the processes essential for developing and conducting a quality clinical trial protocol and providing quality data collection, biostatistical analyses, and a clinical study report, all while maintaining the highest standards of ethics and excellence-- Provided by publisher.

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