1. Record Nr. UNISA990000370760203316

Autore	ACKROYD, Peter
Titolo	Notes for a new culture : an essay on modernism / Peter Ackroyd
Pubbl/distr/stampa	London : Vision, c1976
Descrizione fisica	152 p. ; 23 cm
Collana	Vision critical studies
Disciplina	941.0859
Collocazione	VII.3.B. 1756(Ri B 49)
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia

2. Record Nr. UNINA9910458853903321

Autore	Peace Karl E. <1941, >
Titolo	Clinical trial methodology / / Karl E. Peace, Ding-Geng (Din) Chen
Pubbl/distr/stampa	Boca Raton : , : Chapman and Hall/CRC Press, , 2011
ISBN	0-429-14207-2 1-58488-918-7
Descrizione fisica	1 online resource (422 p.)
Collana	Chapman & Hall/CRC biostatistics series ; ; 35
Altri autori (Persone)	ChenDing-Geng
Disciplina	615.5072/4
Soggetti	Clinical trials Drugs - Testing Electronic books.
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
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 Processand Regulation of Clinical Trials; Chapter 3: Ethical

Considerations in the Designand Conduct of Clinical Trials; Chapter 4: Sample Size Considerations in ClinicalTrials Pre-Market Approval; Chapter 5: Sequential, Group Sequential, StochasticCurtailment, and Adaptive DesignProcedures 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 InferenceChapter 10: Bioequivalence Clinical Trials; Chapter 11: Dose and Frequency Determinationfrom Phase II Clinical Trials in StressTest-Induced Angina; Chapter 12: Confirmation of Clinically Optimal Dosingin the Treatment of Duodenal Ulcers:A Phase III Dose Comparison Trial; Chapter 13: Pivotal Proof-of-Efficacy Clinical Trialsin the Prevention of NANSAID-InducedGastric Ulceration; Chapter 14: Clinical Trials in the Treatmentof Alzheimer's Disease Based uponEnrichment Designs; Chapter 15: A Clinical Trial to Establish Reductionof CHD Risk
Chapter 16: Pivotal Proof-of-Efficacy Clinical Trialsin the Treatment of Panic DisorderChapter 17: Combination Clinical Trials; Chapter 18: Monitoring Clinical Trials for Adverse Events; Index; Back cover

Sommario/riassunto

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.