1. Record Nr. UNINA9910778685003321

Titolo	Clinical trials handbook [[electronic resource] /] / edited by Shayne Cox Gad
Pubbl/distr/stampa	Hoboken, NJ, : Wiley, c2009
ISBN	1-282-36844-3 9786612368448 0-470-46636-7 0-470-46635-9
Descrizione fisica	1 online resource (1247 p.)
Collana	Pharmaceutical Development Series ; ; v.8
Altri autori (Persone)	GadShayne C. <1948->
Disciplina	615.1 615.580724 615/.1
Soggetti	Drugs - Testing Clinical trials
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	Clinical Trials Handbook; Contents; Preface; Contributors; 1 Introduction to Clinical Trials; 2 Regulatory Requirements for Investigational New Drug; 3 Preclinical Assessment of Safety in Human Subjects; 4 Predicting Human Adverse Drug Reactions from Nonclinical Safety Studies; 5.1 History of Clinical Trial Development and the Pharmaceutical Industry; 5.2 Adaptive Research; 6 Organization and Planning; 7 Process of Data Management; 8 Clinical Trials Data Management; 9.1 Clinical Trials and the Food and Drug Administration; 9.2 Phase I Clinical Trials; 9.3 Phase II Clinical Trials 9.4 Designing and Conducting Phase III Studies9.5 Phase IV: Postmarketing Trials; 9.6 Phase IV and Postmarketing Clinical Trials; 9.7 Regulatory Approval; 9.8 New Paradigm for Analyzing Adverse Drug Events; 10.1 Clinical Trials in Interventional Cardiology: Focus on XIENCE Drug-Eluting Stent; 10.2 Clinical Trials Involving Oral Diseases; 10.3 Dermatology Clinical Trials; 10.4 Emergency Clinical Trials; 10.5 Gastroenterology; 10.6 Gynecology Randomized Control Trials; 10.7 Special Population Studies (Healthy Patient Studies); 10.8

Musculoskeletal Disorders; 10.9 Oncology
10.10 Pharmacological Treatment Options for Nonexudative and Exudative Age-Related Macular Degeneration10.11 Paediatrics; 10.12 Clinical Trials in Dementia; 10.13 Clinical Trials in Urology; 10.14 Clinical Trials on Cognitive Drugs; 10.15 Bridging Studies in Pharmaceutical Safety Assessment; 10.16 Brief History of Clinical Trials on Viral Vaccines; 11 Methods of Randomization; 12 Randomized Controlled Trials; 13 Cross-Over Designs; 14.1 Biomarkers; 14.2 Biomarkers in Clinical Drug Development: Parallel Analysis of Alzheimer Disease and Multiple Sclerosis; 15 Review Boards
16 Size of Clinical Trials17 Blinding and Placebo; 18 Pharmacology; 19 Modeling and Simulation in Clinical Drug Development; 20 Monitoring; 21 Inference Following Sequential Clinical Trials; 22 Statistical Methods for Analysis of Clinical Trials; 23 Explanatory and Pragmatic Clinical Trials; 24.1 Ethics of Clinical Research in Durg Trials; 24.2 Ethical Issues in Clinical Research; 25 Regulations; 26 Future Challenges in Design and Ethics of Clinical Trials; 27 Proof-of-Principle/Proof-of-Concept Trials in Drug Development; Index

Sommario/riassunto

Best practices for conducting effective and safe clinical trials Clinical trials are arguably the most important steps in proving drug effectiveness and safety for public use. They require intensive planning and organization and involve a wide range of disciplines: data management, biostatistics, pharmacology, toxicology, modeling and simulation, regulatory monitoring, ethics, and particular issues for given disease areas. Clinical Trials Handbook provides a comprehensive and thorough reference on the basics and practices of clinical trials. With contributions from a range of