

1. Record Nr.	UNINA9910455072803321
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 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	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 Studies 9.5 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 Degeneration 10.11 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 Trials 17 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 Drug 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

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#### 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

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2. Record Nr.	UNISALENT0991000797349707536
Autore	Vanderbei, Robert J.
Titolo	Linear programming : foundations and extensions / Robert J. Vanderbei
Pubbl/distr/stampa	Boston ; London ; Dordrecht : Kluwer Academic Publishers, c1996
ISBN	0792398041
Descrizione fisica	xviii, 418 p. : ill. ; 24 cm
Collana	International series in operations research & management science ; 4
Disciplina	519.7
Soggetti	Linear programming Mathematical optimization
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Nota di bibliografia	Includes bibliographical references and index