Record Nr. UNINA9910455072803321 Clinical trials handbook [[electronic resource] /] / edited by Shayne Cox **Titolo** 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. Inglese Lingua di pubblicazione **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

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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