Record Nr. UNINA9910816269003321 Autore Julious Steven A Titolo An introduction to statistics in early phase trials / / Steven Julious, Say-Beng Tan, David Machin Chichester, West Sussex;; Hoboken, NJ,: John Wiley, 2010 Pubbl/distr/stampa **ISBN** 1-282-48277-7 9786612482779 0-470-68616-2 0-470-31917-8 Edizione [1st ed.] Descrizione fisica 1 online resource (271 p.) Altri autori (Persone) MachinDavid <1939-> TanSay Beng Disciplina 610.15195 615/.19012 Soggetti Drugs - Testing - Statistical methods Clinical trials - Statistical methods 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 An Introduction to Statistics in Early Phase Trials; Contents; Chapter 1 Early phase trials; Chapter 2 Introduction to pharmacokinetics; Chapter 3 Sample size calculations for clinical trials; Chapter 4 Crossover trial basics; Chapter 5 Multi-period crossover trials; Chapter 6 First time into man; Chapter 7 Bayesian and frequentist methods; Chapter 8 Firsttime-into-new-population studies; Chapter 9 Bioequivalence studies; Chapter 10 Other Phase I trials; Chapter 11 Phase II trials; general issues; Chapter 12 Dose-response studies; Chapter 13 Phase II trials with toxic therapies Chapter 14 Interpreting and applying early phase trial resultsChapter 15 Go/No-Go criteria; Appendix; References; Index Sommario/riassunto All new medicines and devices undergo early phase trials to assess,

interpret and better understand their efficacy, tolerability and safety. An Introduction to Statistics in Early Phase Trials describes the practical design and analysis of these important early phase clinical trials and provides the crucial statistical basis for their interpretation. It clearly and concisely provides an overview of the most common types of trials

undertaken in early phase clinical research and explains the different methodologies used. The impact of statistical technologies on clinical development and t