1. Record Nr.   UNINA9910816269003321

Autore   Julious Steven A

Titolo   An introduction to statistics in early phase trials / / Steven Julious, Say-Beng Tan, David Machin

Pubbl/distr/stampa   Chichester, West Sussex ; ; Hoboken, NJ, : John Wiley, 2010

ISBN   9786612482779
9781282482777
1282482777
9780470686164
0470686162
9780470319178
0470319178

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 First-time-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