

1. Record Nr.	UNINA9910254078203321
Autore	Hamasaki Toshimitsu
Titolo	Group-Sequential Clinical Trials with Multiple Co-Objectives // by Toshimitsu Hamasaki, Koko Asakura, Scott R. Evans, Toshimitsu Ochiai
Pubbl/distr/stampa	Tokyo : , : Springer Japan : , : Imprint : Springer, , 2016
ISBN	4-431-55900-0
Edizione	[1st ed. 2016.]
Descrizione fisica	1 online resource (118 p.)
Collana	JSS Research Series in Statistics, , 2364-0057
Disciplina	615.50724
Soggetti	Statistics Statistical Theory and Methods Statistics for Life Sciences, Medicine, Health Sciences Statistics for Social Sciences, Humanities, Law
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 at the end of each chapters.
Nota di contenuto	1. Introduction -- 2. Early Stopping for Efficacy in Clinical Trials with multiple co-primary endpoints -- 3. Sample size recalculation based on observed effects at interim -- 4. Early stopping for futility in Clinical Trials with multiple co-primary endpoints -- 5. Early stopping for futility or Efficacy in Clinical Trials with multiple co-primary endpoints -- 6. Clinical Trials with multiple primary endpoints -- 7. Group-sequential designs for three-arm noninferiority clinical trials -- 8. Further development: topics not covered in this book.
Sommario/riassunto	This book focuses on group sequential methods for clinical trials with co-primary endpoints based on the decision-making frameworks for: (1) rejecting the null hypothesis (stopping for efficacy), (2) rejecting the alternative hypothesis (stopping for futility), and (3) rejecting the null or alternative hypothesis (stopping for either futility or efficacy), where the trial is designed to evaluate whether the intervention is superior to the control on all endpoints. For assessing futility, there are two fundamental approaches, i.e., the decision to stop for futility based on the conditional probability of rejecting the null hypothesis, and the other based on stopping boundaries using group sequential methods. In this book, the latter approach is discussed. The book also briefly deals with the group sequential methods for clinical trials designed to

evaluate whether the intervention is superior to the control on at least one endpoint. In addition, the book describes sample size recalculation and the resulting effect on power and type I error rate. The book also describes group sequential strategies for three-arm clinical trials to demonstrate the non-inferiority of experimental intervention to actively control and to assess the assay sensitivity to placebo control.
