

1. Record Nr.	UNINA9910300112903321
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Titolo	Modern Dose-Finding Designs for Cancer Phase I Trials: Drug Combinations and Molecularly Targeted Agents // by Akihiro Hirakawa, Hiroyuki Sato, Takashi Daimon, Shigeyuki Matsui
Pubbl/distr/stampa	Tokyo : , : Springer Japan : , : Imprint : Springer, , 2018
ISBN	4-431-55573-0
Edizione	[1st ed. 2018.]
Descrizione fisica	1 online resource (XIII, 89 p. 3 illus.)
Collana	JSS Research Series in Statistics, , 2364-0065
Disciplina	519.5
Soggetti	Biometry Statistics Biostatistics Statistical Theory and Methods
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Nota di contenuto	1. Introduction -- 2. Phase I Trials for Drug Development in Oncology -- 3. A Summary of Dose -- Finding Methods in Standard Phase I Trials -- 4. Phase I Trials for Combination of Two Agents -- 5. Phase I Trials for Joint Assessment of Both Efficacy and Toxicity -- 6. Additional Topics on Adaptive Dose -- Finding Methods.
Sommario/riassunto	This book deals with advanced methods for adaptive phase I dose-finding clinical trials for combination of two agents and molecularly targeted agents (MTAs) in oncology. It provides not only methodological aspects of the dose-finding methods, but also software implementations and practical considerations in applying these complex methods to real cancer clinical trials. Thus, the book aims to furnish researchers in biostatistics and statistical science with a good summary of recent developments of adaptive dose-finding methods as well as providing practitioners in biostatistics and clinical investigators with advanced materials for designing, conducting, monitoring, and analyzing adaptive dose-finding trials. The topics in the book are mainly related to cancer clinical trials, but many of those topics are potentially applicable or can be extended to trials for other diseases. The focus is mainly on model-based dose-finding methods for two

kinds of phase I trials. One is clinical trials with combinations of two agents. Development of dose-finding methods for two-agent combination trials requires reasonable models that can adequately capture joint toxicity probabilities for two agents, taking into consideration possible interactions of the two agents on toxicity probability such as synergistic or antagonistic effects. Another is clinical trials for evaluating both efficacy and toxicity outcomes in single- and two-agent combination trials. These methods are often applied to the phase I trials including MTAs because the toxicity and efficacy for a MTA does not monotonically increase with dose, but the efficacy often increases initially with the dose and then plateaus. Successful software implementations for several dose-finding methods are introduced in the book, and their operating characteristics in practice are discussed. Recent advance of the adaptive dose-finding methods in drug developments are also provided.

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