1.	Record Nr.	UNINA9910484444203321
	Titolo	Design and Analysis of Subgroups with Biopharmaceutical Applications / / edited by Naitee Ting, Joseph C. Cappelleri, Shuyen Ho, (Din) Ding-Geng Chen
	Pubbl/distr/stampa	Cham : , : Springer International Publishing : , : Imprint : Springer, , 2020
	ISBN	3-030-40105-7
	Edizione	[1st ed. 2020.]
	Descrizione fisica	1 online resource (404 pages)
	Collana	Emerging Topics in Statistics and Biostatistics, , 2524-7743
	Disciplina	615.10727
	Soggetti	Biometry Pharmaceutical chemistry Biostatistics Pharmaceutics
	Lingua di pubblicazione	Inglese
	Formato	Materiale a stampa
	Livello bibliografico	Monografia
	Nota di contenuto	1. Data-driven and Confirmatory Subgroup Analysis in Clinical Trials -- 2. Subgroup Analysis – A View from Industry -- 3. Biomarker-Targeted Confirmatory Trials -- 4. Considerations on Subgroup Analysis in Design and Analysis of Multi-Regional Clinical Trials -- 5. Practical Subgroup Identification Strategies in Late-stage Clinical Trials -- 6. Exploratory Subgroup Identification for Biopharmaceutical Development -- 7. Logical Inference on Treatment Efficacy When Subgroup Exists -- 8. The GUIDE Approach to Subgroup Identification and Inference -- 9. Use of the VG (Virtual Twins Combined with GUIDE) Method in the Development of Precision Medicines -- 10. Subgroups Identification for Tailored Therapies: a System of Methods, a Framework for Consistent Methodology Evaluation, and an Integrated Learn-and-confirm Approach -- 11. Developing and Validating Predictive Classifiers in Randomized Clinical Trials -- 12. Issues Related to Subgroup Analysis -- 13. Subgroup Analysis with Partial Linear Model -- 14. Subgroup Analysis in the 21st Century -- 15. Power of Statistical Tests for Subgroup Analysis in Meta-Analysis -- 16. Heterogeneity and Subgroup Analysis in Network Meta-Analysis.

Sommario/riassunto

This book provides an overview of the theories and applications on subgroups in the biopharmaceutical industry. Drawing from a range of expert perspectives in academia and industry, this collection offers an overarching dialogue about recent advances in biopharmaceutical applications, novel statistical and methodological developments, and potential future directions. The volume covers topics in subgroups in clinical trial design; subgroup identification and personalized medicine; and general issues in subgroup analyses, including regulatory ones. Included chapters present current methods, theories, and case applications in the diverse field of subgroup application and analysis. Offering timely perspectives from a range of authoritative sources, the volume is designed to have wide appeal to professionals in the pharmaceutical industry and to graduate students and researchers in academe and government.