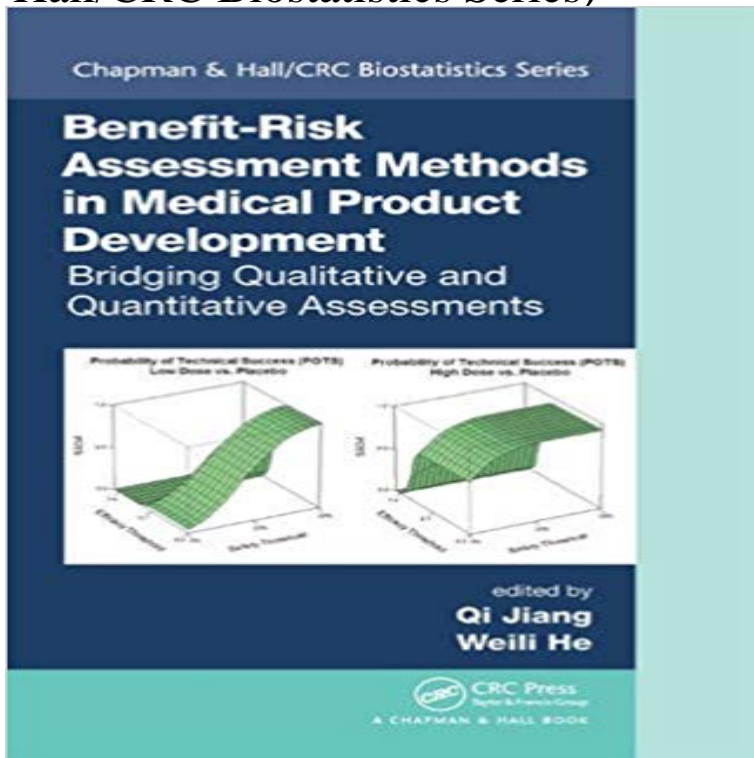


Benefit-Risk Assessment Methods in Medical Product Development: Bridging Qualitative and Quantitative Assessments (Chapman & Hall/CRC Biostatistics Series)



Guides You on the Development and Implementation of BR Evaluations

Benefit-Risk Assessment Methods in Medical Product Development: Bridging Qualitative and Quantitative Assessments provides general guidance and case studies to aid practitioners in selecting specific benefit-risk (BR) frameworks and quantitative methods. Leading experts from industry, regulatory agencies, and academia present practical examples, lessons learned, and best practices that illustrate how to conduct structured BR assessment in clinical development and regulatory submission. The first section of the book discusses the role of BR assessments in medicine development and regulation, the need for both a common BR framework and patient input into BR decisions, and future directions. The second section focuses on legislative and regulatory policy initiatives as well as decisions made at the U.S. FDA's Center for Devices and Radiological Health. The third section examines key elements of BR evaluations in a product's life cycle, such as uncertainty evaluation and quantification, quantifying patient BR trade-off preferences, ways to identify subgroups with the best BR profiles, and data sources used to assist BR assessment. The fourth section equips practitioners with tools to conduct BR evaluations, including assessment methodologies, a quantitative joint modeling and joint evaluation framework, and several visualization tools. The final section presents a rich collection of case studies. With top specialists sharing their in-depth knowledge, thought-provoking considerations, and practical advice, this book offers comprehensive coverage of BR evaluation methods, tools, and case studies. It gives practitioners a much-needed toolkit to develop and conduct their own BR evaluations.

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