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

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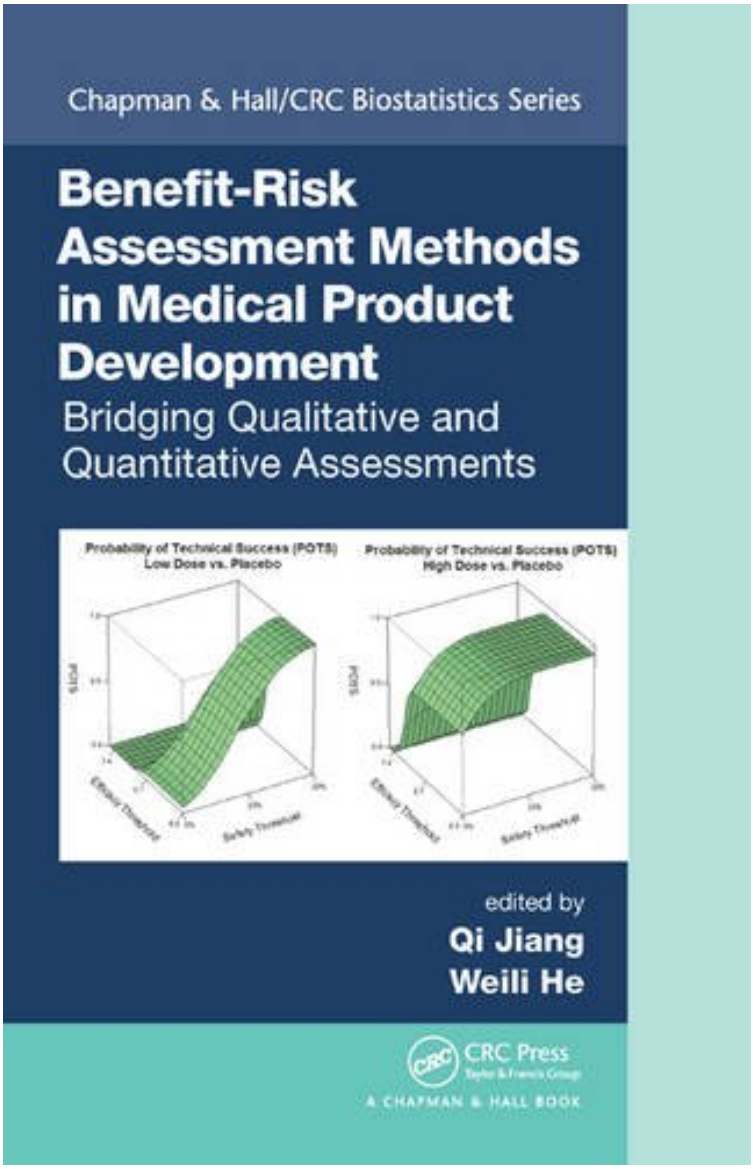

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From Chapman and Hall/CRC : Benefit-Risk Assessment Methods in Medical Product Development: Bridging Qualitative and Quantitative Assessments (Chapman Hall/CRC Biostatistics Series) before purchasing it in order

to gage whether or not it would be worth my time, and all praised 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 BenefitRisk Assessment Methods in Medical Product Development: Bridging Qualitative and Quantitative Assessments provides general guidance and case studies to aid practitioners in selecting specific benefitrisk (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. FDAs Center for Devices and Radiological Health. The third section examines key elements of BR evaluations in a products 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.

"This is one of the few books fully dedicated to the benefitrisk (BR) evaluation of pharmaceutical product. . . This book was edited by two leading experts who not only have done extensive research on the topics but also have established and led the society of clinical trial BR working group. The contributing authors in each chapter are experienced researchers and/or thought-leaders in the field. We think this book gives practitioners a much needed job aid to perform their BR evaluation." ~ Journal of Biopharmaceutical Statistics About the AuthorDr. Qi Jiang is an executive director of Global Biostatistical Science at Amgen. In this role, she is the biostatistical therapeutic area head for oncology and hematology and the lead of the Center of Excellence for Safety and BenefitRisk. In addition, Dr. Jiang provides oversight to Amgens biostatistical efforts in the AsiaPacific region. Before joining Amgen, she worked at the Harvard School of Public Health, Merck, and Novartis. Dr. Jiang is the co-editor of the Chapman Hall/CRC book Quantitative Evaluation of Safety in Drug Development: Design, Analysis and Reporting and the author of more than 60 peer-reviewed publications on method development, study design, and data analysis and reporting. She is a fellow of the American Statistical Association, a co-lead of the American Statistical Association Biopharmaceutical Section Safety Working Group, a co-lead of the Quantitative Sciences in the Pharmaceutical Industry (QSPI) BenefitRisk Working Group, and an associate editor for Statistics in Biopharmaceutical Research. Dr. Weili He is a director of clinical biostatistics at Merck Co., Inc. Her research interests include survival and longitudinal data modeling, missing data imputation, cancer Phase I and II designs, repeated categorical data modeling, surrogate marker evaluations, adaptive design methodologies and implementations, and methods for benefitrisk assessment. Dr. He has published extensively in the areas of adaptive designs and benefitrisk evaluations and is the author of more than 50 peer-reviewed publications in statistical and medical journals. She is also a lead editor of the book Practical Considerations for Adaptive Trial Design and Implementation. She has been actively involved in many professional activities and services, including serving as co-chair of the Quantitative Sciences in the Pharmaceutical Industry (QSPI) BenefitRisk Working Group, co-chair of the DIA Adaptive Design Scientific Working Group (ADSWG) KOL lecture series, associate editor for Statistics in Biopharmaceutical Research, and a referee for other statistical journals.