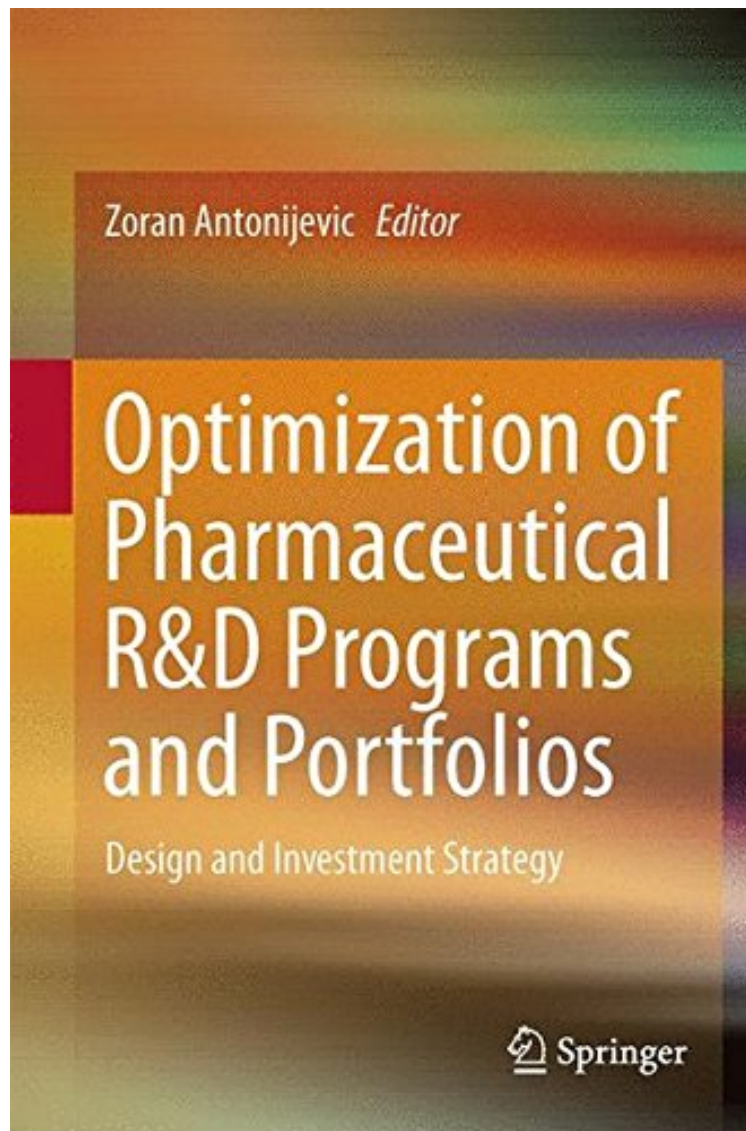


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## Optimization of Pharmaceutical RD Programs and Portfolios: Design and Investment Strategy

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Very little has been published on optimization of pharmaceutical portfolios. Moreover, most of published literature is coming from the commercial side, where probability of technical success (PoS) is treated as fixed, and not as a consequence of development strategy or design. In this book there is a strong focus on impact of study design on PoS and ultimately on the value of portfolio. Design options that are discussed in different chapters are dose-selection strategies, adaptive design and enrichment. Some development strategies that are discussed are indication sequencing, optimal number of programs and optimal decision criteria. This book includes chapters written by authors with very broad backgrounds including financial, clinical, statistical, decision sciences, commercial and regulatory. Many authors have long held executive positions and have been involved with decision making at a product or at a portfolio level. As such, it is expected that this book will attract a very broad audience, including decision makers in pharmaceutical RD, commercial and financial departments. The intended audience also includes portfolio planners and managers, statisticians, decision scientists and clinicians. Early chapters describe approaches to portfolio optimization from big Pharma and Venture Capital standpoints. They have stronger focus on finances and processes. Later chapters present selected statistical and decision analysis methods for optimizing drug development programs and portfolios. Some methodological chapters are technical; however, with a few exceptions they require a relatively basic knowledge of statistics by a reader.

From the Back Cover Very little has been published on optimization of pharmaceutical portfolios. Moreover, most of the published literature comes from the commercial perspective, where probability of technical success (PoS) is treated as fixed, and not as a consequence of development strategy or design. In this book there is a strong focus on the impact of study design on PoS, and ultimately a portfolios value. Design options that are discussed are dose-selection strategies, adaptive design, and enrichment. Some development strategies that are examined are indication sequencing, optimal number of programs, and optimal decision criteria. This book includes chapters written by authors with very broad backgrounds including financial, clinical, statistical, decision sciences, commercial, and regulatory. Many authors have long held executive positions and have been involved with decision making at a product or at a portfolio level. As such, it is expected that this book will attract a very broad audience, including decision makers in pharmaceutical RD, commercial, and financial departments. The intended audience also includes portfolio planners and managers, statisticians, decision scientists, and clinicians. Early chapters describe approaches to portfolio optimization from big pharma, and venture capital standpoints, focusing on finances and processes. Later chapters present selected statistical and decision analysis methods for optimizing drug development programs and portfolios. Some methodological chapters are technical; however, with a few exceptions they require a basic knowledge of statistics by a reader. About the Author Zoran Antonijevic is a Senior Director at Cytel Consulting with responsibility for strategic advice at trial, program, or portfolio level. His research areas include: adaptive design, pharmaceutical portfolio optimization, and decision-making within clinical drug development process. Zoran has 20 years of experience in drug development. His prior experience includes positions at Harvard School of Public Health, GlaxoSmithKline, and Quintiles Innovation where his primary responsibility was to develop designs and approaches that maximize probability of success for programs and/or maximize product's value. He also has extensive experience with performing due-diligence, and as a member of product portfolio executive teams. Externally, Zoran is the chair of DIA Adaptive Design Scientific Working Group.