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Nota di contenuto	Prologue -- Preface -- Overview -- Approaches to utilising decision-making framework -- Benefit-risk assessment of medicines by pharmaceutical companies and regulatory authorities -- Development of a universal benefit-risk framework and template -- Implementation of the benefit-risk assessment template by mature agencies -- Implementation of the benefit- risk summary template by a maturing agency: A case study -- Communicating benefit-risk decisions by US FDA, EMA, TGA and Health Canada -- Conclusions and future directions -- References.
Sommario/riassunto	This book proposes and investigates a universal framework, and accompanying documentation system, to facilitate and catalogue benefit-risk decisions; a valuable addition to the benefit-risk toolbox. Over the past decade, pharmaceutical companies and regulatory agencies have been reviewing the benefit-risk assessment of medicines with a view to developing a structured, systematic, standardized approach. Examining the evaluation of such an approach by several mature regulatory authorities ensures that the reader gains a unique

insight into the ongoing debate in this area. The field of benefit-risk assessment continues to evolve at a rapid pace due to political and societal pressure, as is reflected in the recent FDA PUDFA agreement as well as in the EMA 2015 Roadmap. Rather than provide a comprehensive snap-shot of this constantly changing environment, this book evaluates selected current approaches to benefit-risk assessment. The strengths and weaknesses of publicly available documents in communicating benefit-risk decisions to stakeholders are reviewed, and these evaluations are used to inform development of a prospective framework that could be used to harmonise procedures globally.