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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

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