



Benefit-Risk Assessment in Pharmaceutical Research and Development (Chapman & Hall/CRC Biostatistics Series)

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Many practitioners in the pharmaceutical industry are still largely unfamiliar with benefit-risk assessment, despite its growing prominence in drug development and commercialization. Helping to alleviate this knowledge gap, **Benefit-Risk Assessment in Pharmaceutical Research and Development** provides a succinct overview of the key considerations relevant to benefit-risk assessment across the pharmaceutical R&D spectrum, from early clinical development to late-stage development to regulatory review to post-launch assessment.

The book first presents interpretations of benefit and risk in the context of a molecule moving from preclinical evaluation into its early testing in humans. It next considers benefit and risk characterization and assessment during a molecule's journey from its clinical evaluation in humans through its submission to regulators for marketing approval. Throughout these sections, the book offers insight into the role of benefit-risk assessment in heightening understanding among key stakeholders by shaping questions and guiding discussions among scientists, physicians, developers, and regulatory agencies. The book also focuses on a molecule's entry into the marketplace as a drug available for consumption by people. It explores the role of benefit-risk assessment as the relevance of carefully collected clinical efficacy and safety metrics fades in the wake of real-world use and evidence of effectiveness and safety.

Bringing together the expertise of 15 contributors from academia and the industry, this book offers an easy-to-read guide to the various facets of benefit-risk assessment in the major stages of pharmaceutical R&D. Suitable for those in both technical and managerial roles, it enables readers to communicate more effectively across their development chain as well as rationally and thoughtfully embed benefit-risk assessment into their R&D processes.

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