

Quantitative Evaluation of Safety in Drug Development: Design, Analysis and Reporting (Chapman & Hall/CRC Biostatistics Series)

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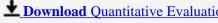
Quantitative Evaluation of Safety in Drug Development: Design, Analysis and Reporting (Chapman & **Hall/CRC Biostatistics Series**)

State-of-the-Art Methods for Drug Safety Assessment

Responding to the increased scrutiny of drug safety in recent years, Quantitative Evaluation of Safety in **Drug Development: Design, Analysis and Reporting** explains design, monitoring, analysis, and reporting issues for both clinical trials and observational studies in biopharmaceutical product development. It presents the latest statistical methods for drug safety assessment.

The book's three sections focus on study design, safety monitoring, and data evaluation/analysis. The book addresses key challenges across regulatory agencies, industry, and academia. It discusses quantitative approaches to safety evaluation and risk management in drug development, covering Bayesian methods, effective safety graphics, and risk-benefit evaluation.

Written by a team of experienced leaders, this book brings the most advanced knowledge and statistical methods of drug safety to the statistical, clinical, and safety community. It shares best practices and stimulates further research and methodology development in the drug safety area.



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