Risk-Based Monitoring and Fraud Detection in Clinical Trials Using JMP and SAS

Richard C. Zink

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Risk-Based Monitoring and Fraud Detection in Clinical Trials Using JMP and SAS Richard C. Zink Improve efficiency while reducing costs in clinical trials with centralized monitoring techniques using JMP and SAS.

International guidelines recommend that clinical trial data should be actively reviewed or monitored; the well-being of trial participants and the validity and integrity of the final analysis results are at stake. Traditional interpretation of this guidance for pharmaceutical trials has led to extensive on-site monitoring, including 100% source data verification. On-site review is time consuming, expensive (estimated at up to a third of the cost of a clinical trial), prone to error, and limited in its ability to provide insight for data trends across time, patients, and clinical sites. In contrast, risk-based monitoring (RBM) makes use of central computerized review of clinical trial data and site metrics to determine if and when clinical sites should receive more extensive quality review or intervention.

Risk-Based Monitoring and Fraud Detection in Clinical Trials Using JMP and SAS presents a practical implementation of methodologies within JMP Clinical for the centralized monitoring of clinical trials. Focused on intermediate users, this book describes analyses for RBM that incorporate and extend the recommendations of TransCelerate Biopharm Inc., methods to detect potential patient-or investigator misconduct, snapshot comparisons to more easily identify new or modified data, and other novel visual and analytical techniques to enhance safety and quality reviews. Further discussion highlights recent regulatory guidance documents on risk-based approaches, addresses the requirements for CDISC data, and describes methods to supplement analyses with data captured external to the study database.

Given the interactive, dynamic, and graphical nature of JMP Clinical, any individual from the clinical trial team - including clinicians, statisticians, data managers, programmers, regulatory associates, and monitors - can make use of this book and the numerous examples contained within to streamline, accelerate, and enrich their reviews of clinical trial data.

The analytical methods described in Risk-Based Monitoring and Fraud Detection in Clinical Trials Using JMP and SAS enable the clinical trial team to take a proactive approach to data quality and safety to streamline clinical development activities and address shortcomings while the study is ongoing.

This book is part of the SAS Press

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