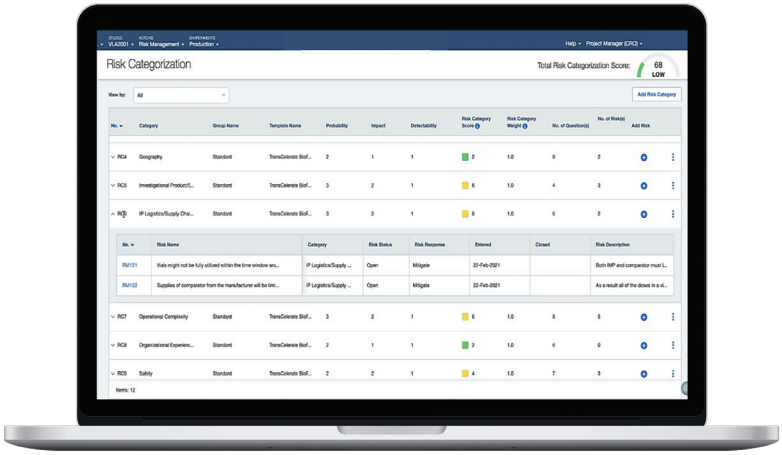
Medidata Risk Management – Enabling Patient Safety and Data Integrity



Medidata Risk Management supports the growing complexity of clinical trials by enabling proactive study design that includes defining and monitoring Quality Tolerance Limits (QTLs). Medidata supports you by designing quality into your clinical trials rather than a reactionary approach of monitoring quality in your trials.

By adopting a risk-based approach to clinical studies, your trial teams can identify, and report risks associated with critical data and processes that enable you to answer key questions and support sound decision-making while protecting study subjects.

Now you can develop cross-functional quality management into protocol design as well as study operations and execution.

Product Benefits

By adopting a risk-based approach to clinical studies, your trial teams can identify risks associated with critical data and processes that need to be monitored for Good Clinical Practice (GCP). Now Medidata Risk Management can help you achieve:

Proactive Risk Management

- Global clinical trials require flexible solutions that can meet evolving study requirements, local regulatory guidelines, and can be deployed through a variety of hardware and deployment models

Risk Reporting

- Study teams need the ability to easily analyze data and demonstrate study oversight activities within the Clinical Study Report (CSR)

Greater Visibility

- Patient safety and data integrity are ensured by monitoring risks in one central location to support enhanced transparency to issues across all your clinical trials

Communication is Key

- Operational teams effectively communicate what matters most across cross-functional teams to ensure consistent and aligned operational execution and continuous improvement efforts

Features

Built on the Medidata Clinical Cloud™

Allows end-to-end solutions for data capture, data management, trial planning, trial management, and analytics and enables a holistic Risk Based Quality Management (RBQM) implementation.

Risk Scoring

Enables risk categorization assessment so severity, impact and detectability are evaluated, and a risk score is calculated.

Powerful Risk Repository

Identifies and evaluates risk across critical data, critical processes and Critical to Quality (CtQ) factors to ensure patient safety and data integrity.

Quality Tolerance Limits (QTLs)

Helps define corresponding risk control mechanisms and performance oversight metrics, such as Key Risk Indicators (KRIs) and QTLs, to make deviations easier to identify.

Identified Mitigation Strategies

Records mitigation strategies so study teams can proactively respond when issues start to develop.

Reporting

Enables better cross-functional tracking, oversight, and accountability through powerful visualization tools.

THE MEDIDATA RBQM SOLUTION: MODULAR & SCALABLE

The Medidata Advantage

Companies struggle using spreadsheets for Risk Management since they are manual, siloed and have security issues. Medidata Risk Management centralizes information, calculates risk scores and monitors results based on KRIs and QTLs, to easily identify anomalies and outliers.

Medidata makes RBQM program development easier by providing a modular approach that meets your requirements today, while being able to scale additional functionality as needed. Built on the Medidata Clinical Cloud, we can share data between solutions to create more efficiencies and collaboration for better business decisions and patient safety.