

Medidata Rave RBQM

Unify your RBQM Strategy

Executing a risk-based quality management (RBQM) approach to monitoring is no longer optional, it is imperative. A successful RBQM strategy requires integration and harmonization across multiple data sources and complex workflows, yet is often constrained by technology, change management and budget.

Medidata is unifying RBQM, delivering the ability to define and execute a holistic, end-to-end risk-based quality management and monitoring strategy from initial protocol development to database lock.

Rave RBQM enables a streamlined process of risk-based quality management through a suite of applications leveraging a modular and scalable approach.

A comprehensive solution designed to meet RBQM Requirements

Rave RBQM is designed to help optimally adhere to ICH E6 (R2) and ICH E8 (R1) recommendations and meet RBQM requirements.

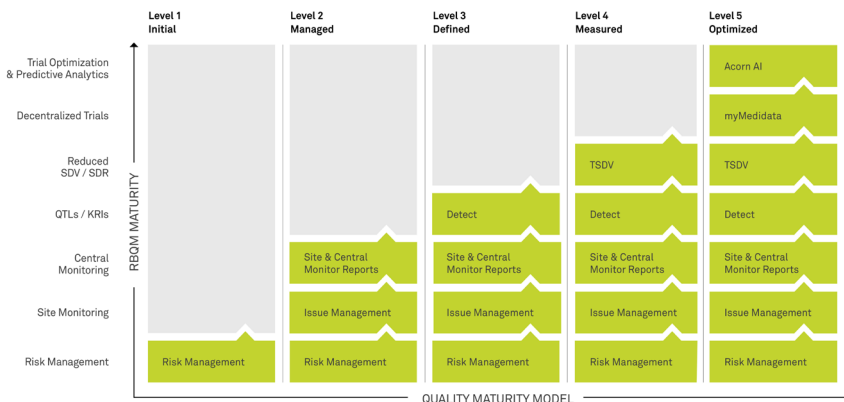
It ensures inspection-ready status and full transparency to regulatory authorities while maintaining continuous application of risk management and centralized statistical monitoring methodologies.

Holistic, modular and scalable

Critical to operationalizing the RBQM approach is a robust platform ecosystem that eliminates the risk of dropped workflows, costly integrations or inefficient data movement across disparate systems.

Rave RBQM is a suite of applications enabling end-to-end, modular and scalable for fully traceable, closed-loop, risk management planning and collaboration of clinical trials.

Modular and Scalable: An Ecosystem of Solutions



THE VALUE OF A FULLY UNIFIED RISK-BASED QUALITY MANAGEMENT SOLUTION

Accelerated RBQM Adoption

- Flexible model to work with the solutions you already have in place
- System and data-agnostic for easy integration
- Purpose-built, user-friendly interface
- Collaborative workflows with in-system alerts, actions and tracking

Enriched Data Quality and Patient Safety

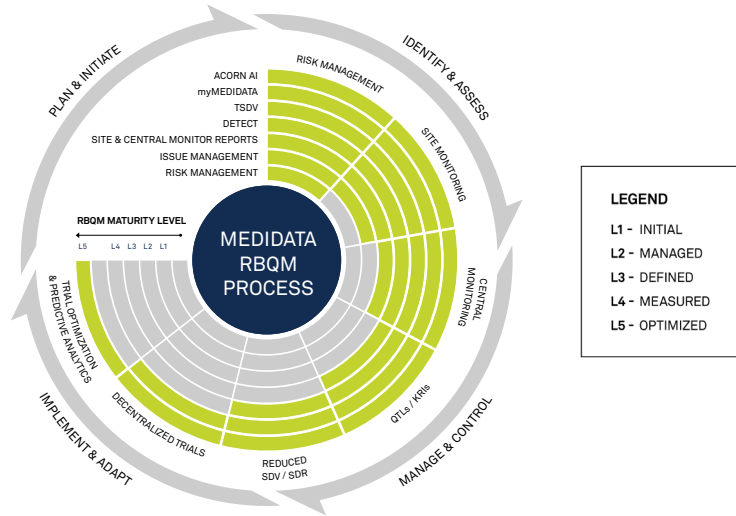
- Continuous quality improvement with proactive, unique insights
- Advanced proprietary algorithms to find known and unknown outliers and trends across multiple variables
- Configurable workflows, KRIs, and study and site specific SDV/SDR plans

Reduced Cost of Ownership

- Cost and burden reduction through use of single vendor
- Minimal long term maintenance

Each module of Rave RBQM is designed with built-in workflows and alerts that enable effective collaboration on a global scale. Master data enables the design of core configuration requirements that establish a fully automated, auditable and scalable solution.

The Comprehensive Solution Designed to Meet RBQM Requirements



LEGEND	
L1 -	INITIAL
L2 -	MANAGED
L3 -	DEFINED
L4 -	MEASURED
L5 -	OPTIMIZED

Enabling Quality Risk Management

UNIFIED ON A DATA DRIVEN PLATFORM

- Built to embed quality risk management principles into daily operations
- Streamlined RBQM workflow for improved productivity
- Accessible across all patients and studies

MODULAR AND SCALABLE

- Flex and integrate into your existing RBQM processes and solutions
- Adopt or remove RBQM components as study needs change

SYSTEMATIC DRIVERS OF CHANGE

- Provides intuitive integration for seamless data flow and information sharing vs. forced processes
- Enables change management through integrated workflow capabilities
- Supported by industry-leading change management experts who will optimize your process and fit supporting systems

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,500 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

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