

# Medidata RBQM – Your Path to Clinical Operations Excellence



Medidata [RBQM \(Risk-Based Quality Management\)](#) provides the technology and experience to transform your approach to clinical operations towards risk-based study execution models. Now you can continuously monitor data from anywhere, allowing you to innovate and optimize your approach to trial design, physical and virtual interactions with sites, and holistic portfolio strategy. Medidata RBQM leverages our experience in data acquisition and aggregation to contextually surface real-time insights at the patient, study, and industry benchmark level, improving Clinical Operations decision making.

All the Medidata RBQM suite of solutions ([Risk Management](#), [Detect](#), [Remote Source Review](#) and [Rave TSDV](#)) work together to help you adhere to ICH E6 (R2) and ICH E8 (R1) recommendations for meeting RBQM requirements. Medidata RBQM is fully configurable and scalable, so you can confidently make adjustments and decide what the right clinical operations strategy is for your trial because you have the technology to support it.

## Benefits of Medidata’s Risk-Based, Quality Approach to Clinical Operations

Plan for trial risks, move from insights to action, and foster intentional, high-value interactions with sites using Medidata RBQM.

### Enable trial virtualization

- Optimize physical interaction with sites based on targeted need

### Eliminate manual tracking and data re-entry

- Single-entry platform that embeds risk planning and data insights into daily operations

### Achieve real-time actionable insights

- Centralized data analytics tell you where to take action with sites

### Reduce implementation and integration challenges

- End-to-end holistic solution eliminates point integrations

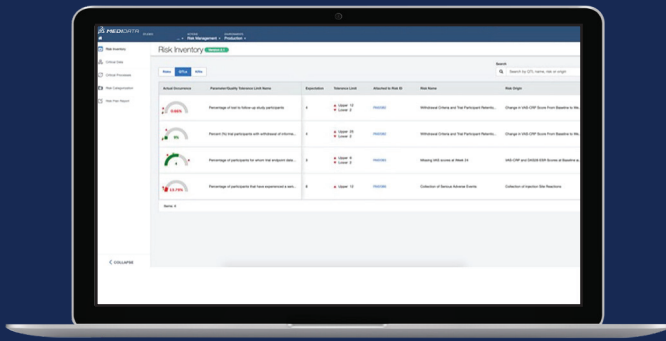
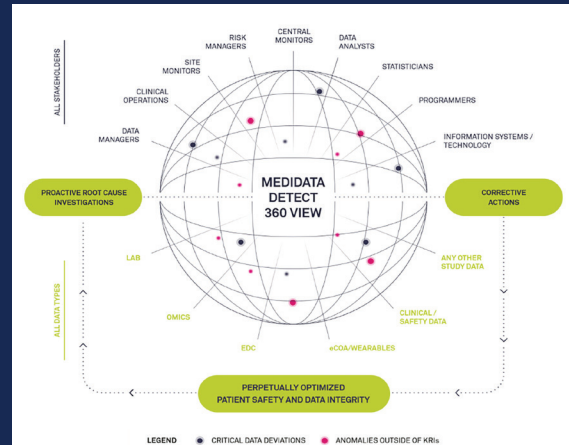
# Features of Medidata RBQM

## Built on the Medidata Clinical Cloud™

- End-to-end solutions for data capture and management, trial planning and management, and analytics - all powered by Medidata RBQM

## Powered by deep analytics through Medidata Detect

- The most powerful, real-time anomaly detection tool, which works with any EDC source, and leverages Key Risk Indicators (KRIs) and Quality Tolerance Limits (QTLs) for easier issue identification



Connected and configurable workflows from study design through execution

**Proactive risk management and reporting**

**Targeted source data verification (TSDV)**

**Centralized statistical monitoring**

**Site monitoring and centralized issue management**

## The Medidata Advantage

Clinical Operations is evolving at the pace of the research it supports. Optimized clinical trial operations are a key differentiator for delivering high-quality treatments, on-time and efficiently. Companies with sound processes for centralized monitoring, optimized source data verification, as well as flexible on-site interactions, are agile to adjust within complex environments as a result of the ever-changing clinical development landscape.

By layering in systems that address the fundamental maturity of their processes, these companies can realize optimized trial design, continual data quality review, early risk, and issue detection, and an improved relationship with the sites, on a scale not seen historically in clinical trials. Medidata RBQM supports excellence in trial execution, enabling companies to achieve digital oversight, which Medidata sees as the future of Clinical Trial Operations.

Medidata, a Dassault Systèmes company, is leading the digital transformation of life sciences.

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