Rave RBQM: Paving the Way to the New Risk-based Approach

Monitoring is more than just "Monitoring"

Monitoring no longer just means managing data quality on site. Traditional, often inefficient monitoring processes can result in overlooked errors, compromised data quality, increased risk and costly study delays... The industry recognizes that this process is, in general, low-value.

Fortunately, with guidance from TransCelerate and ICH E6 (R2) GCP addendum, there is light at the end of the tunnel. With these new guidelines, a risk-based approach to monitoring (RBQM) is no longer optional, but rather, imperative. This approach is intended to guide centralized monitoring teams identify key risks that impact the success of a protocol, thus enabling them to concentrate on those known risks instead of implementing a one-size-fits-all approach where clinical research associates (CRAs) check every box.

Rave RBQM Enables Data Quality Management

At Medidata, we view RBQM (Risk-based Quality Management) as an end-to-end risk management process essential to meeting the new ICH GCP (E6) addendum, ranging from initial protocol development to database lock. With that in mind, we created **Rave RBQM,** which offers a family of capabilities that life sciences companies need to execute their RBQM strategy. These capabilities combine risk assessment and anomaly detection with centralized issue management, enabling users to identify risks and document actions in real-time.

END-TO-END RISK MANAGEMENT IS ESSENTIAL TO MEET THE ICH GCP (E6) ADDENDUM. THIS INCLUDES:

RISK ASSESSMENT
Assess impact, probability, detectability of study risks. Configure and link KRIs/Analytics

CENTRALIZED ANALYTICS
Review known and unknown risks through the use of statistical, machine-learning analytics. Generate issues/actions

VISIT PREPARATION
CRA reviews issues/actions created by centralized risk monitoring team. Prepared adaptive monitoring plan focused on risks

VISIT CONDUCT
CRA completes assigned tasks including Source Data Review (SDR), root cause analysis and preventative/corrective actions

DOCUMENTATION
Visit conduct responses, associated comments, issues and action items all captured in visit report

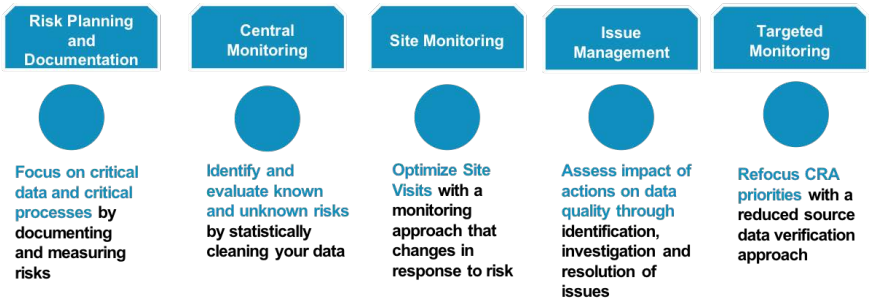
Achieve Smart, Collaborative and Streamlined ICH E6 (R2) GCP compliance with Rave RBQM

Rave RBQM for your Risk-based Monitoring Needs

Rave RBQM offers the ability to define and execute a holistic, end-to-end risk-based quality management and monitoring strategy and is the only comprehensive solution designed to meet RBQM Functional Requirements as defined in TransCelerate's Risk-Based Monitoring Technology Considerations Part 2 (Dec 2015). We have worked closely with Transcelerate members, defining Rave RBQM to help optimally adhere to ICH E6 (R2) guidelines. Rave RBQM ensures logical and statistical data quality across all of your monitoring functions.

Each module of Rave RBQM is designed with built-in work flows and alerts to allow effective collaboration on a global scale. Master data enables the design of core configuration requirements that establish a fully automated, auditable and scalable solution; one featuring comprehensive master data management components with a single source of truth and cross-platform reporting at its core.

Rave RBQM Framework



RISK ASSESSMENT DOCUMENTATION

Medidata RACT (Risk Assessment and Categorization) captures components of a holistic, system-bound integrated quality risk management plan (IQRMP) through centralized documentation of the RACT, key risk indicators (KRIs) configuration and source data review (SDR) and source data verification (SDV) strategies related to the critical data and critical processes. Since Medidata RACT is built on the Medidata Rave Clinical Cloud platform, it enables reuse of RACT information encouraging cross-functional collaboration and deployment of RBQM strategies.

RAVE RBQM: A FULLY UNIFIED RISK-BASED QUALITY MANAGEMENT SOLUTION

Fully traceable, closed-loop, risk management planning and collaboration platform for the next generation of clinical trials.

With **Rave RBQM** you comply with ICH E6 (R2) GCP requirements, provide full transparency to regulatory authorities and maintain inspection-ready status while planning and implementing your risk management and centralized statistical monitoring methodologies.

The Platform of Choice for Clinical Research

The Medidata Rave Clinical Cloud is the cutting-edge platform that transforms the clinical trial experience for patients, sponsors, CROs, and research sites. Designed with a unified data platform, the Rave Clinical Cloud creates a single source of truth for all study-related data. Simply put, enter data once and let the platform master and populate it throughout the end-to-end suite of Rave applications. Optimize operational execution, decrease the data entry and maintenance burden, and reduce the number of clinical systems across your study teams. Throw away your list of passwords, you are now on a truly unified platform.

CENTRAL MONITORING

Rave CSA (Centralized Statistical Analytics) is a unique solution that applies sophisticated, statistical, machine-learning algorithms to interrogate the clinical data in a trial for outliers, data anomalies and trends. CSA identifies areas of risk fast and accurately by providing immediate insight into clinical trial performance and data quality.

SITE MONITORING

Medidata Site Monitoring facilitates efficient monitoring of clinical studies to provide clinical research associates (CRAs) an advanced user experience and proactive decision-making aid to reduce risk and costs while increasing study and site performance, patient safety, and time to market. These efficiencies are made possible by leading-edge technology that supports multi-tiered monitoring visits driven by risk category, optimal workload management and a structured data approach to monitoring visit reports. The reduction in redundant data entry saves a tremendous amount of time completing reports, regardless if they are on-site or remote.

ISSUE MANAGEMENT

Medidata Issue Management is a centralized, cross-functional module for the management of all issues and associated action items throughout the clinical study. It ensures maximum collaboration across the clinical team and gives the ability to re-assign, copy stakeholders and add ongoing comments as the issue moves through mitigation strategies.

TARGETED MONITORING

Rave TSDV (Targeted Source Data Verification) ensure adherence to planned targeted monitoring strategies. Rave TSDV efficiently reduces the amount of SDV conducted using a configurable, statistical algorithm without sacrificing regulatory compliance or data quality strategies.

Benefits of Rave Risk-based Quality Management

ENRICHED DATA QUALITY THROUGH EARLY, REAL-TIME AND UNIQUE INSIGHTS

- Analyze millions of data points to identify known and unknown risks, anomalies, outliers and patterns
- Assess impact of actions on data quality through configurable workflows and KRI performance tracking
- Simplify data verification process through configurable study and site-specific SDV/SDR plans

STRENGTHENED CROSS-FUNCTIONAL STUDY-TEAM COLLABORATION

- Allow functional teams to review critical risks centrally
- Track workflows centrally through easy-to-read flags, highlights and alerts
- Manage all cross-functional risk management activities through seamless, end-to-end workflows

INCREASED PERFORMANCE AND RETENTION OF CRAS AND SITES

- Enable CRAs to efficiently prepare for upcoming visits through simplified SDV/SDR plans with advanced tracking
- Provide greater workflow efficiency and reduce administrative burden on CRAs
- Streamline site visits and increase visit reporting productivity by automating routine functions

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 1,400 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers.

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