Medidata Strategic Monitoring: 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 (RBM) 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.

RBM enables end-to-end data quality management

At Medidata, we view RBM 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 the **Medidata Strategic Monitoring Suite**, the only end-to-end comprehensive suite that combines 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 NEW 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 Medidata Strategic Monitoring

Medidata Strategic Monitoring for your RBM Needs

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

Each module of the suite is designed with built-in workflows 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.

Medidata Strategic Monitoring Suite Components

<table>
<tr><th colspan="7">Medidata Strategic Monitoring Suite</th></tr>
<tr><td>Risk Assessment/ Management</td><td colspan="2">Centralized Monitoring</td><td colspan="2">Targeted Monitoring</td><td colspan="2">Site Monitoring</td></tr>
<tr><td>Risk Management</td><td>Patient Profiles</td><td>CSA with Key Risk Indicators</td><td>SDR</td><td>TSDV</td><td>Site Visits</td><td>Monitoring Visit Reports</td></tr>
<tr><td colspan="7">Issue Management and Workflow</td></tr>
<tr><td colspan="7">Alerts and Notifications</td></tr>
<tr><td colspan="7">Master Data</td></tr>
</table>

RISK ASSESSMENT/MANAGEMENT

Medidata Edge Risk Management captures components of a holistic, system-bound integrated quality risk management plan (IQRMP) through centralized documentation of risk assessment and categorization (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. Edge Risk Management assesses impact, probability and detectability of study risks — a key step in the risk-based monitoring approach. Edge Risk Management includes built-in workflow and electronic approvals to generate an Integrated Quality Risk Management Plan (IQRMP).

MEDIDATA STRATEGIC MONITORING: A FULLY UNIFIED RISK-BASED MONITORING SUITE

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

With **Medidata Strategic Monitoring** you can 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.

CENTRALIZED MONITORING

Medidata Edge Central Monitoring (CM) 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. Edge CM identifies areas of risk fast and accurately by providing immediate insight into clinical trial performance and data quality. In addition, KRIs configured in Edge Risk Management display as part of the centralized dashboard, enabling resources to identify risks and launch a series of correct action workflows. CSA is specifically designed for centralized statistical monitoring across various functional areas.

TARGETED MONITORING

Medidata Source Data Review (SDR) and **Medidata Targeted Source Data Verification (TSDV**) ensure adherence to planned targeted monitoring strategies. SDR functionality confirms whether critical processes defined in the protocol were executed by research sites in compliance with ICH guidelines and ALCOA principles. TSDV efficiently reduces the amount of SDV conducted using a configurable, statistical algorithm without sacrificing regulatory compliance or data quality strategies.

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 AND WORKFLOW

Medidata Edge 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.

Benefits of Medidata Strategic Monitoring

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 Solutions

Medidata is leading the digital transformation of life sciences with the world's most-used platform for clinical development, commercial and real-world data. Powered by artificial intelligence and delivered by #1 ranked industry experts, the Intelligent Platform for Life Sciences helps pharmaceutical, biotech, medical device companies and academic researchers accelerate value, minimize risk and optimize outcomes. Medidata serves more than 1,000 customers and partners worldwide and empowers more than 100,000 certified users every day to create hope for millions of patients. Discover the future of life sciences: **www.mdsol.com**

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