WHITE PAPER

Revvity: Risk-Based Monitoring

revvity signals

Risk-Based Monitoring

The FDA has been encouraging an innovative, centralized and statistically driven approach to monitoring clinical trials to enhance human subject protection and the quality of trial data. Yet the pace of data generation, and the complexity and volume of the data produced, has exceeded the capabilities of most existing informatics solutions. Program, country, and study managers, CRAs, clinical monitors and clinical trial managers, clinical data managers, CROs, and others need informatics solutions that help them focus on sites in greatest need, based on risk.

RESPOND TO RISK

The challenge for people involved in monitoring a clinical trial, and all its associated data, has been ineffective and costly 100 percent source-data verification and schedule-driven monitoring. A centrally and statistically-driven approach lets central and remote monitors and CRAs quickly and easily monitor and score the most critical data and processes across the study and, as a result, target their activities where they can be most impactful. This alleviates issues of insufficient resources to support analysis, wasted resources, difficulty detecting trends and outliers, poor visibility into site performance and operational metrics, and, ultimately, studies not being completed on time or submissions being rejected.

MARKET AND REGULATORY TRENDS AFFECTING MONITORING

Risk-based monitoring addresses forces that have been adding data complexity to clinical trials including:

- Adoption of risk-based approaches to quality in the ICH E6 R2 guidelines
- Increased focus on vendor oversight and traceability in decision making as defined in ICH E6 R2
- Advent of precision medicine and value-based treatment schemes
- Rising use of real-world data to generate product evidence and mHealth data in clinical trials
- Safety and efficacy beyond randomized clinical trials
- Increasingly distributed R&D
- Rapid cloud and mobile adoption

At a Glance

The Revvity Risk-Based Monitoring Solution provides a number of advantages in deploying a risk-based approach to clinical trial oversight.

Adaptive Risk Model

A flexible approach that includes key risk indicator (KRI) definitions, thresholds, weightings, and recommended actions

Advanced and Predictive Analytics

Leverage historical site data to dynamically calculate tolerance limits and thresholds and adjust KRI weightings as trials evolve.

Alignment with TransCelerate's RBM initiative

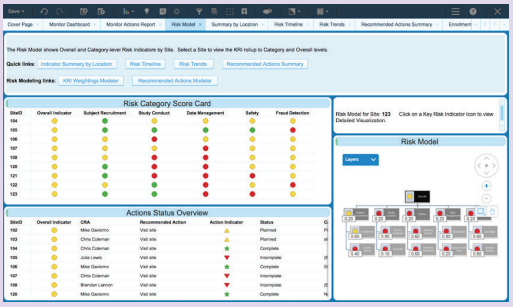
RACT (Risk Assessment and Categorization Tool), traffic light indicators and focus on critical data and processes

Closed-Loop Workflow in One System

- Trigger recommended actions
- Report actions back into the system
- Assess the historical impact of the actions
- Build insights back into the risk model

Leverage Your Historical Data

- Assess the impact of recommended actions over time
- Predict risks and make smarter site selections
- Establish risk tolerance thresholds
- Improve protocol and study design quality



Risk-Based Monitoring dashboard

LEVERAGE DATA-DRIVEN INSIGHTS

The solution to technology challenges and market trends involves using data-driven insights to optimize clinical trial site performance. Revvity's Risk-Based Monitoring (RBM) solution lets clinical monitors easily navigate from high-level overview data to specific data points from multiple source systems.

Powered by TIBCO Spotfire® analytics and visualization software, the RBM solution quickly identifies and tracks actions for high-risk sites, reduces complexity by supporting multiple trial designs and data sources, and optimizes monitoring by using adaptive risk models that apply to historical study data.

REDUCING TIME AND RISK

The RBM solution is proven to accelerate the monitoring process, driving down time, process steps, and costs.

- Reduction in number of major protocol violations – 20-50 percent
- Reduction in underperforming sites – up to 30 percent
- Reduction in time to database lock – 10-30 percent
- Reduction in number of source system integrations – 30-50 percent
- Reduction in IT infrastructure and support costs – up to 67 percent

MONITOR HIGH-RISK SITES

To identify high-risk sites, the RBM solution provides easy-to-use, dynamic visualizations and analytics that are powered by validated statistical models. Actions are automatically recommended based on persona-driven workflows, while vendor oversight is easily managed via dashboards.

REDUCE COMPLEXITY

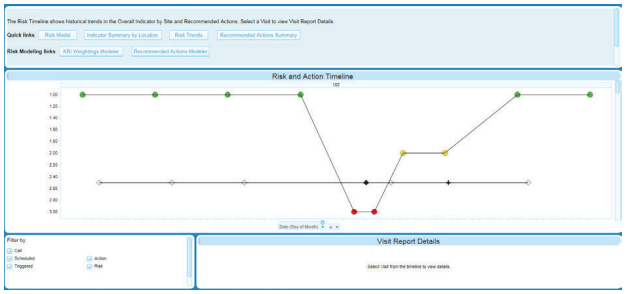
As a single, unified data analytics solution, RBM aids monitors in their risk assessment, from data source to visualization to action. It offers standard and configurable Key Risk Indicators based on industry guidelines and specific protocols, and leverages pre-built data services and data mashups to visualize content from multiple sources.

OPTIMIZE MONITORING

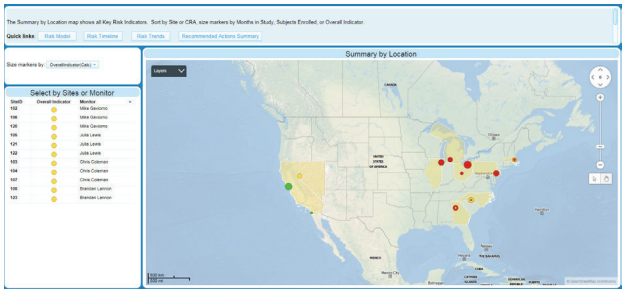
A risk-based approach optimizes monitoring by using adaptive risk models that are applied to historical study data. Fully adjustable thresholds, weighting, and actions improve the risk model while predictive analytics leverage historical data to make smarter site selection decisions, and ultimately improve study/protocol design. The solution also enables a complete audit trail.

Data visualization and analytics is only the beginning of a holistic RBM program. The Revvity Risk-Based Monitoring Solution applies the principles of actionable and adaptive RBM to work in a guided workflow that is specific to the end user's role. In a closed-loop approach, it triggers recommended actions and follow-up in response to risk. It allows the central monitor to evaluate the risk model as a whole, and easily adjusts weightings, thresholds, and recommended actions accordingly.

Revvity provides a one-stop-shop for clinical data insights including clinical data review, risk-based monitoring, drug safety, and clinical operations. Revvity Signals is the exclusive distributor of TIBCO Spotfire® for life sciences companies world-wide. TICBO Spotfire® is used by 23 of the 25 largest pharmaceutical and biotech companies and ten of the top 15 clinical research organizations to draw insights from clinical data. Customers benefit by accessing the TIBCO Spotfire® superior technology coupled with Revvity Signals deep domain knowledge and intellectual property. Because many Life Sciences R&D organizations have already adopted TIBCO Spotfire®, those organizations can easily embed Revvity's clinical solutions into their existing analytics infrastructure and processes.



Site performance profile showing risk trigger, action and action impact.



Geographic map with sites and risk levels.

Adopt a proactive approach to risk management of clinical trials with The Revvity's Risk-Based Monitoring Solution.

Visit https://revvitysignals.com/solutions/clinical-analytics

Revvity Signals Software, Inc
77 4th Avenue | Waltham, MA 02451 USA
P: (800) 762-4000 or (+1) 203-925-4602
revvitysignals.com/company/contact

revvity signals