

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

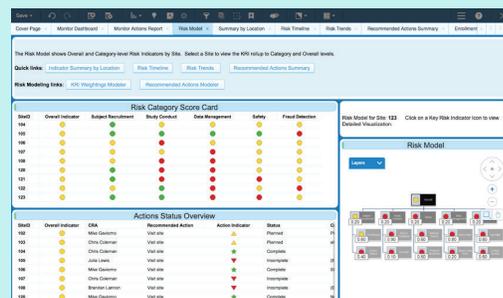
RACT (Risk Assessment and Categorization Tool), traffic light indicators and focus on critical data and processes

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

