Risk-Based Quality Management: Assess, Manage, and Review Risk across Studies and Sites

Continuously identify safety, efficacy, operational, study, and site risks.

Fine-tune your Ability to Manage Risk Remotely

Make better decisions using mitigation plans and statistical monitors, which sit on top of advanced and adjustable KRIs.

Ideal for:

- Clinical Operations
- Clinical Innovation
- Remote/Central Monitoring
- Clinical Data Quality Specialists

Saama delivers an end-to-end solution that continuously engages users across the study lifecycle, from design and conduct to evaluation and reporting. With risk assessment plans, anomaly detection, automatic notifications, a collaborative tasking system, and built-in KRIs and QTLs, RBQM sets you up for success in managing and mitigating risk.

Solution Highlights

- Initiate risk assessment early, using a reusable, industry-standard risk assessment and categorization tool (RACT)
- Proactively track changes to KPIs/KRIs for different functional groups (site management, subject health/safety, data quality, etc.) from a single oversight scorecard
- Manage issues and tasks in app, or in third party applications, based on perceived risk and actual evidence
- Investigate risk categories with visual indicators for incomplete or inaccurate data

Your One-Stop Shop for Automated Risk Mitigation

To enhance patient safety and data quality in clinical trials, FDA guidance recommends that sponsors develop comprehensive risk-based monitoring strategies. Saama gives you everything you need in a single solution.

Risk Assessment

Saama's Risk Assessment Categorization Tool (RACT) delivers standard and custom templates to identify risk categories and subcategories by phase, program, and therapeutic area. Color-coded risk indicators and weights help central monitors, data managers, and operations leads visually identify issues within specific risk areas, and thresholds and weights can be adjusted to determine to what extent risks may impact the overall health of a trial.

Risk Monitoring

Remote statistical and event-based monitoring of integrated data means that anomalies can be detected much faster. Advanced predictive KRIs, well-defined QTLs, push notifications, auditable task generation, and full configurabile drilldowns to dashboards and KRIs streamline workflows so you can resolve issues much more quickly.

Risk Review

Saama's convenient Risk Scorecard makes it easy to summarize performance in real time, at the portfolio, program, country, vendor, study, or site level. Filters and drilldown capabilities make it easy to understand and communicate your data, and the flexible solution can measure study-specific metrics, risks, and thresholds against enterprise-wide standards.

Get Started Now

RBQM can be up and running in just four weeks from time of data access.
To learn more and arrange a demo, **contact Saama today.**

About Saama Technologies, Inc.

Saama is the #1 AI clinical analytics platform company, enabling the life sciences industry to conduct faster and safer clinical development and regulatory programs. Today, 50 biotech companies—including many of the top 20 pharmaceutical companies—use Saama's award-winning Life Science Analytics Cloud (LSAC) platform to accelerate more than 1,500 studies. LSAC's rich applications facilitate unprecedented and authoritative oversight of comprehensive clinical research data, enabling companies to file New Drug Applications (NDAs) more efficiently and bring drugs to market faster. Discover more at www.saama.com and follow Saama @SaamaTechInc on Twitter.

sales@saama.com
www.saama.com
+1 888.205.3500