caidya®

Protect Your Innovation
Accelerate Your Success

Caidya's RBQM isn't just a compliance exercise, it's a strategic advantage, keeping you inspection-ready and ahead of potential issues from day one. We safeguard data integrity, protocol compliance and patient safety factors while accelerating timelines and reducing costs. We are leading experts in preventing Critical to Quality (CtQ) errors and our proactive approach integrates risk management throughout your trial lifecycle.

Why Caidya RBQM?

→ **Faster, Safer Trials** – Early detection of risks means faster resolution, fewer delays, and improved patient safety

→ **Proven Efficiency Gains** – Reduce costly site visits and source data verification (SDV) without compromising quality

→ **Regulatory Alignment** – Fully compliant with ICH E6 (R3) and global authority guidance (FDA, EMA, MHRA, NMPA)

→ **Data You Can Trust** – Protects data integrity and delivers actionable insights in real time
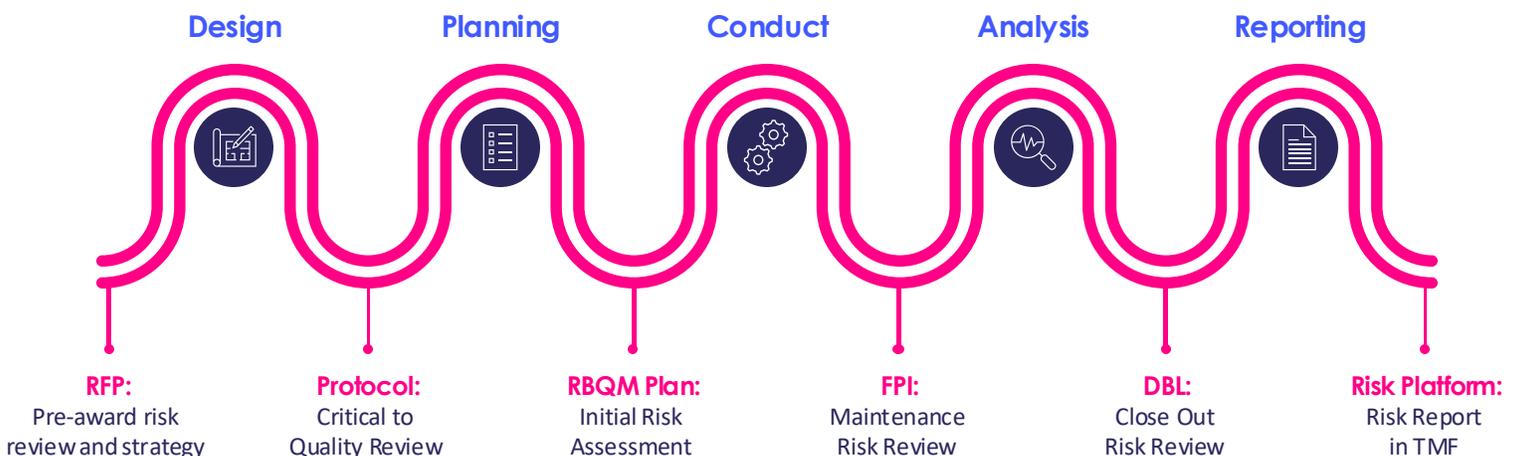
Central Risk Management – Your Quality Command Center

Gain complete visibility into your trial's risk profile— so you can make confident, informed decisions at every stage

Every Caidya full-service trial has a dedicated Central Risk Manager who:

✓ Oversees risk assessment from protocol review through database lock

✓ Monitors Critical to Quality (CtQ) factors to prevent meaningful errors

✓ Ensures real-time adaptation to emerging risks

Caidya's End-to-End Risk Management Process

Design	Planning	Conduct	Analysis	Reporting

| **RFP:** Pre-award risk review and strategy | **Protocol:** Critical to Quality Review | **RBQM Plan:** Initial Risk Assessment | **FPI:** Maintenance Risk Review | **DBL:** Close Out Risk Review | **Risk Platform:** Risk Report in TMF |

Central Monitoring – Smarter Oversight, Better Outcomes

We combine central, on-site, and remote monitoring to create a tailored strategy that maximizes vigilance and efficiency. Using Medidata Clinical Data Studio, we apply AI, machine learning, and advanced analytics to:

→ Reduce on-site monitoring costs, expedite time to database lock, and increase confidence in your trial outcomes

→ Detect anomalies, outliers, and data trends earlier than traditional methods

→ Set Acceptable Ranges such as Quality Tolerance Limits (QTLs) and Key Risk Indicators (KRIs) that trigger proactive action

→ Identify and resolve potential quality issues before they impact trial integrity

The Caidya Advantage:

✓ Tailored to You: RBQM plans built for your study's unique design, complexity, and endpoints

✓ Enhances quality, data integrity, project oversight, patient safety, and inspection readiness

✓ Reduce SDV whilst maintaining data vigilance

✓ Proactively identify fraud, duplicate data, date variances, rounding and propagation errors, under- and over- reporting, and event incidence trends

✓ Confidence in CtQ factors

Central Monitoring Methods

QTL
Quality Tolerance Limit
Identify systematic study level issues that can impact subject safety or reliability of trial results

KRI
Key Risk Indicator
Used to monitor identified risk exposures over time on a study/region/site, or participant level

Statistical Analysis
Enables review of aggregate data for data veracity and reporting patterns

Exploratory Analysis
Enables proactive review of compliance, reporting, safety, and data integrity

Ready to safeguard your study and speed your path to success?

Let's discuss how Caidya RBQM can accelerate your innovation.