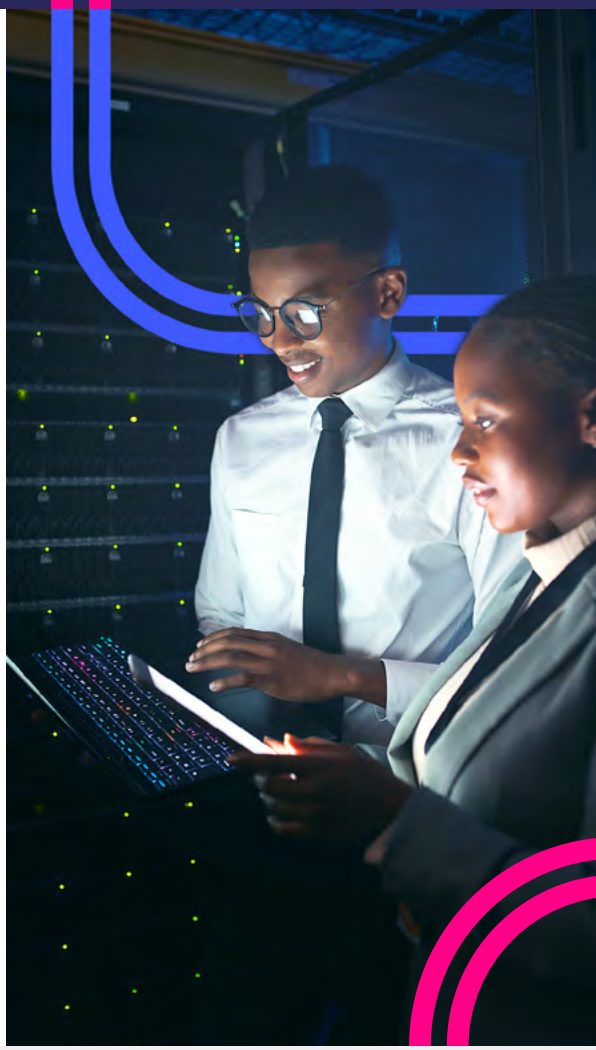
Quality Risk Management and Central Monitoring

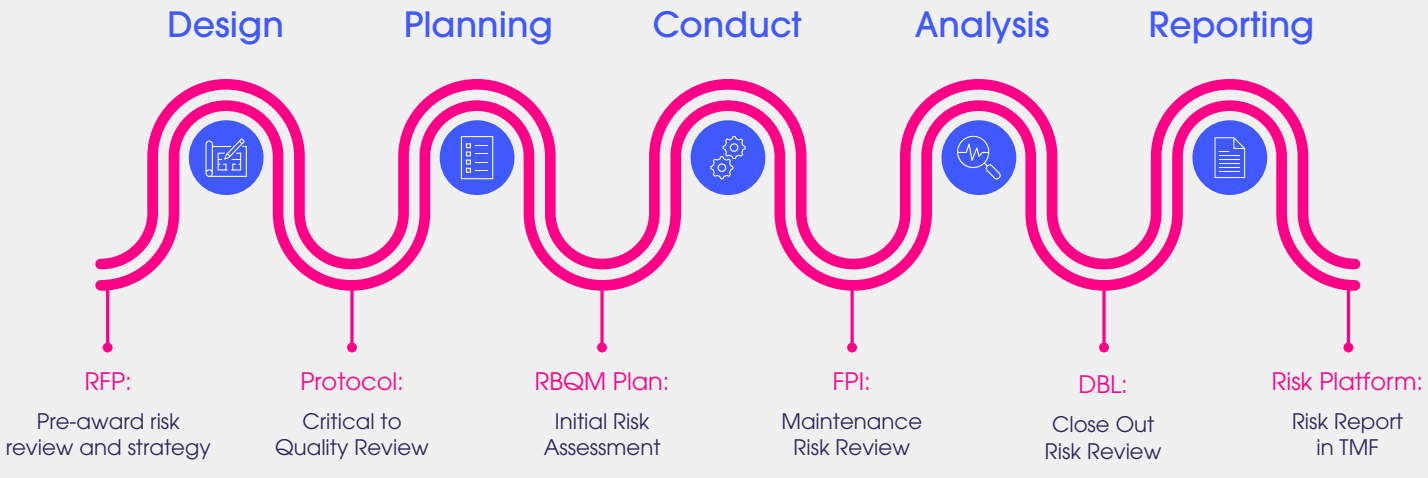
Risk control strategies are essential for any organization, as they help to prevent risks from becoming issues.

By prioritizing Critical-to-Quality (CtQ) factors in risk management control, organizations can prevent the incidence of meaningful errors that may jeopardize patient safety and data integrity. This is in line with International Conference on Harmonization (ICH) Good Clinical Practice (GCP) requirements E6 and E8 for trial conduct. Risk control strategies help organizations to ensure compliance with these regulations, as well as improve patient safety and data integrity.

Caidya conducts risk management by following a mandatory process which involves a cross-functional, collaborative approach for risk identification, evaluation, control, communication, review, and reporting. Central Risk Managers facilitate and organize this process and create risk-based quality management (RBQM) plans. Risks and risk control strategies have assigned owners responsible for implementation of measures and oversight of status, observations, and action triggers, which are tracked on our Risk Management Platform.



Caidya's End-to-End Risk Management Process



Central Monitoring

What is it?

Central Monitoring is an effective way to review aggregate data to ensure high quality clinical trials, identify anomalies, and detect systematic and significant errors and potential data manipulation or data integrity issues. It is an integral element of a Risk-Based Quality Management strategy, which can facilitate reduced or targeted Source Data Verification.

How is it done?

A Central Monitoring Manager, working in conjunction with the Central Risk Manager, Project Manager, Clinical Trial Manager, Data Manager, Medical Monitor, and statisticians, will develop a Central Monitoring Strategy. This strategy will detail the process for central surveillance of data and the requirements for targeted Source Data Verification. Advanced software systems are used to implement Centralized Monitoring on a study, site, and regional level. Key Risk Indicators and Quality Tolerance Limits are developed based on critical to quality factors with defined thresholds and triggers for predetermined action. Statistical and exploratory analysis of the data will identify anomalies and outliers. The Central Monitoring Manager typically conducts a full central monitoring review monthly and communicates and escalates findings and actions with the project team functional leads and client.

What are the benefits?

Central Monitoring enhances quality, data integrity, project oversight, patient safety, confidence in critical to quality factors, and inspection readiness. It may also create cost efficiencies by reducing the extent and/or frequency of on-site monitoring visits. It can proactively identify fraud, duplicate data, date variances, rounding and propagation errors, under and over reporting, and event incidence trends. It ensures proactive identification and resolution of emergent issues.

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

KRIs are used to monitor identified risk exposures over time on a study/region/site or participant level

Statistical Analysis

Review of aggregate data for data veracity and reporting patterns

Exploratory Analysis

Proactive review following triggers or flags