

Building Sustainable RBQM Frameworks: Challenges, Metrics, and Real-World Results



PP21

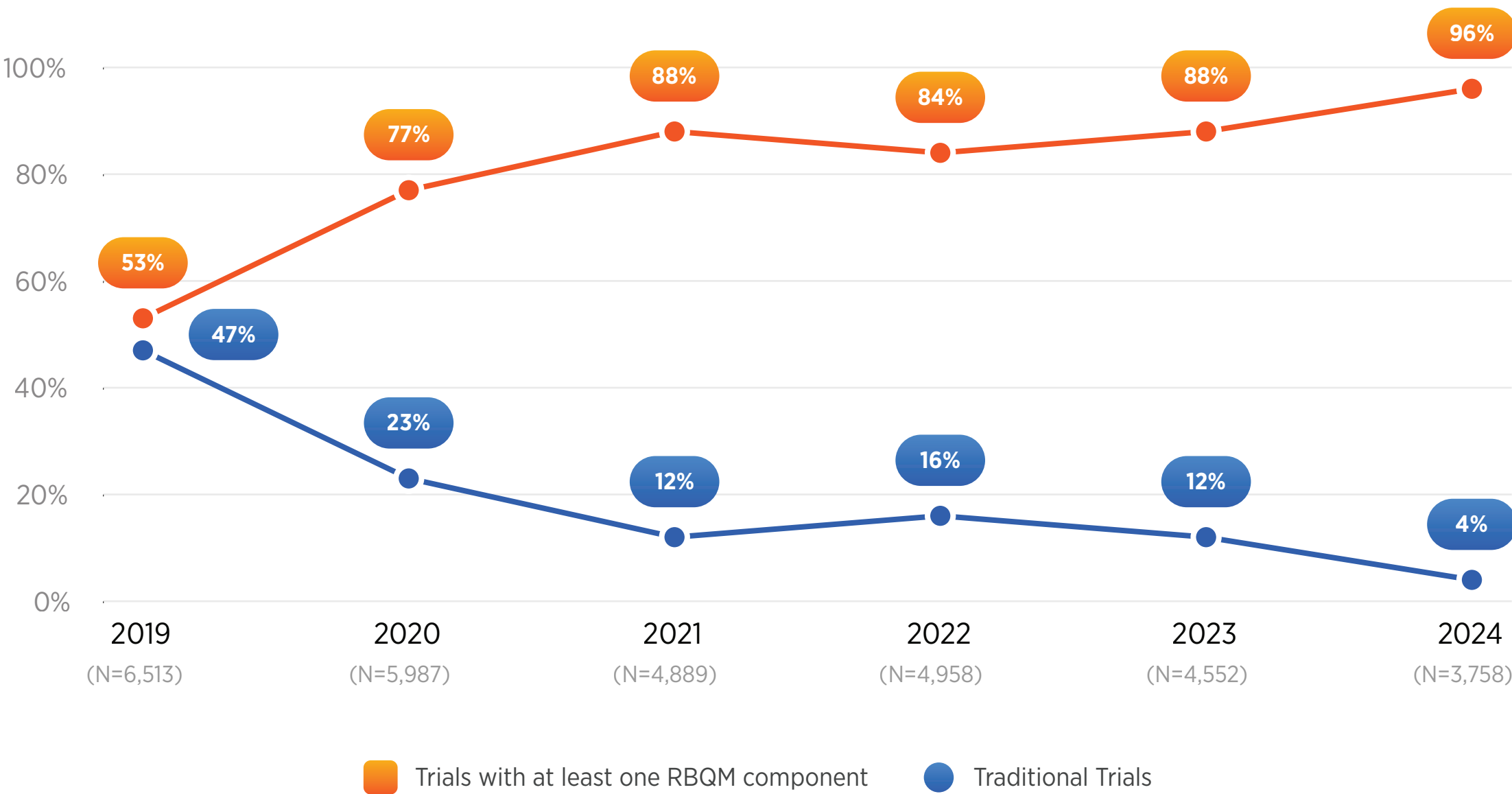
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Background & Rationale

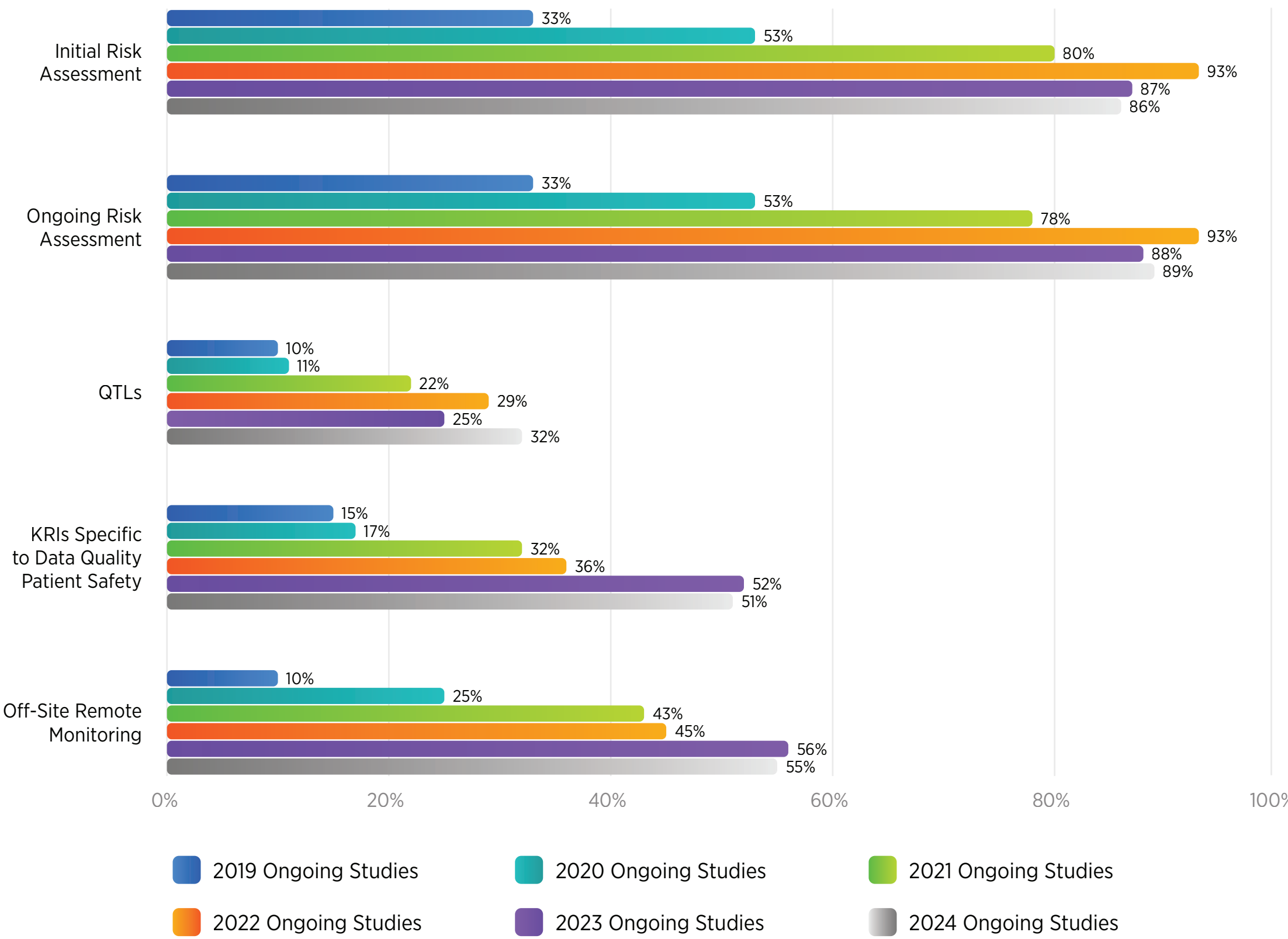
Why Risk-Based Quality Management Matters

Risk-based quality management (RBQM) is designed to focus oversight on what matters most to data integrity and patient safety. While adoption is increasing, evidence demonstrating how RBQM performs in practice remains critical to advancing maturity and confidence in these approaches.

Increasing Adoption of RBQM Components in Clinical Trials



Prevalence of RBM & RBQM Components in Ongoing Studies



Visuals adapted from ACRO 2025 RBQM Report
https://www.acrohealth.org/wp-content/uploads/2025/06/ACRO_2025-RBQM-Report_Final-062425.pdf

Objective

Evaluating the Impact of Central Monitoring within an RBQM Framework

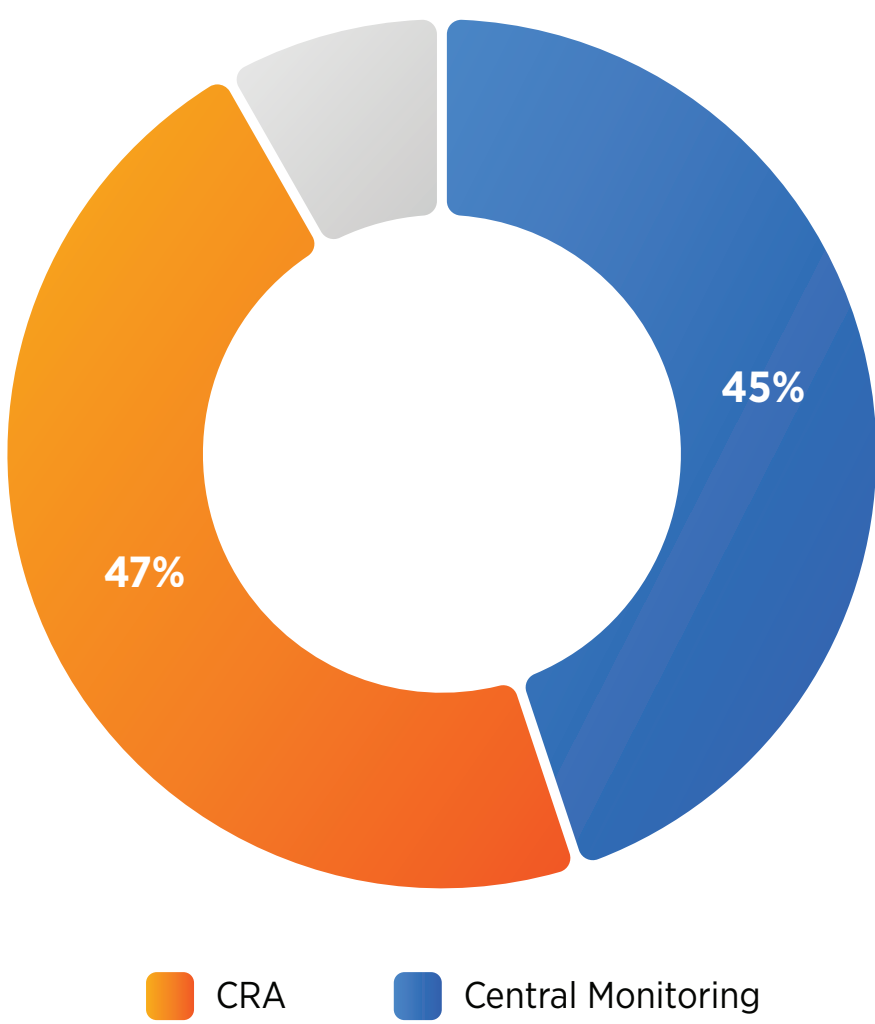
This analysis evaluates whether central monitoring enables earlier identification of protocol deviations (PDs) compared with traditional CRA-led detection, and how RBQM metrics can be used to support effective oversight and monitoring resource allocation across global trial operations.

Real-World Case Study

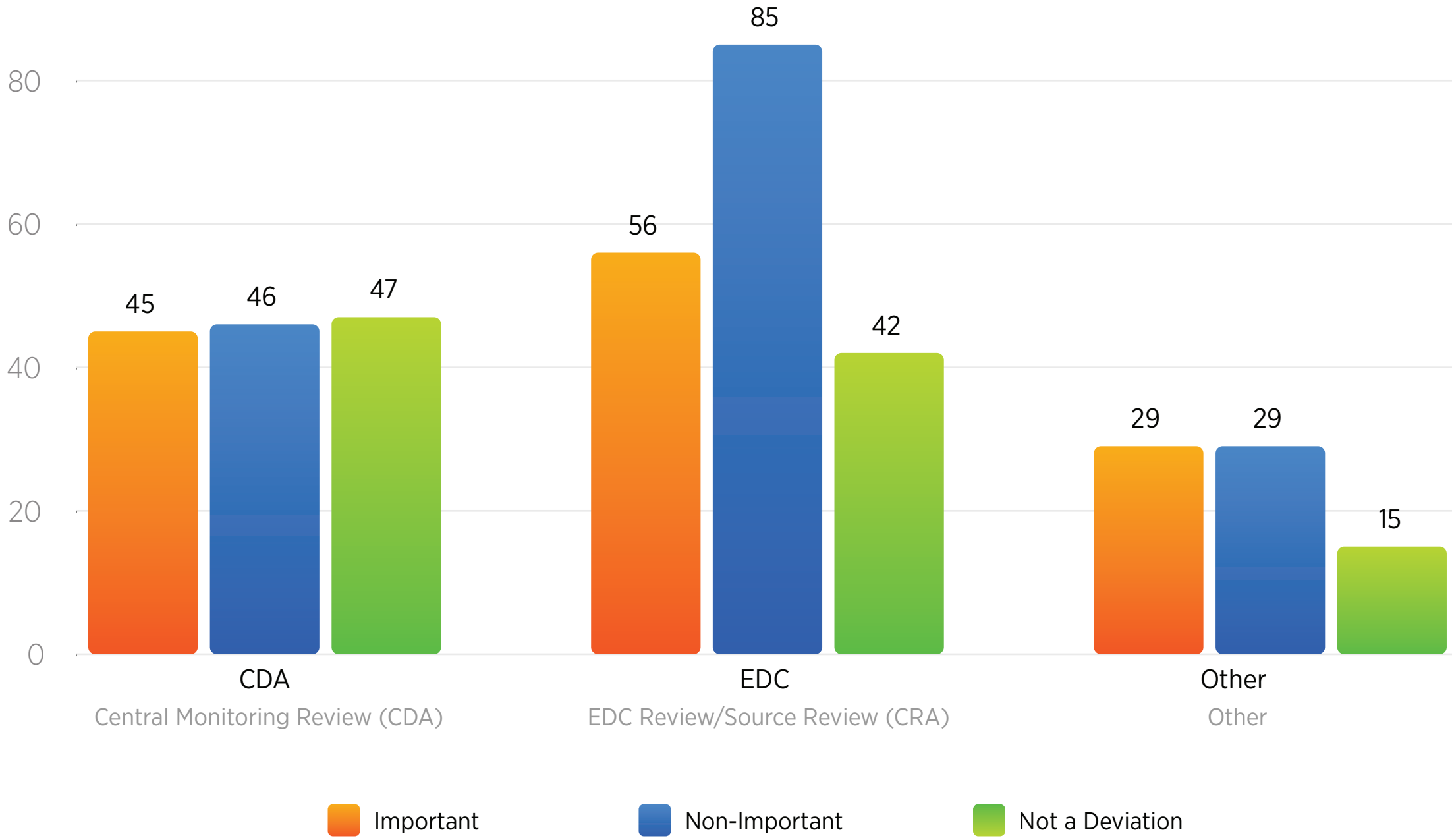
RBQM in Practice: Central Monitoring Assessment

A real-world case example illustrates how centralized monitoring activities, conducted by global monitoring teams, were used to identify, review, and act on risk signals within an RBQM framework. Centralized review supported targeted site follow-up and more efficient use of on-site monitoring resources. Internal cost modeling indicates centralized monitoring resources may be approximately **54% lower cost on average** than traditional on-site CRA resources; estimates vary by study design and geography.

% of Total PD's Identified by Source



Average Days to PD Identification by Source



Key Metrics Assessed

Measuring RBQM Performance

- Percentage of PDs identified through central monitoring
- Time to PD detection: Central monitors vs CRAs
- Distribution of Important vs Non-Important PDs

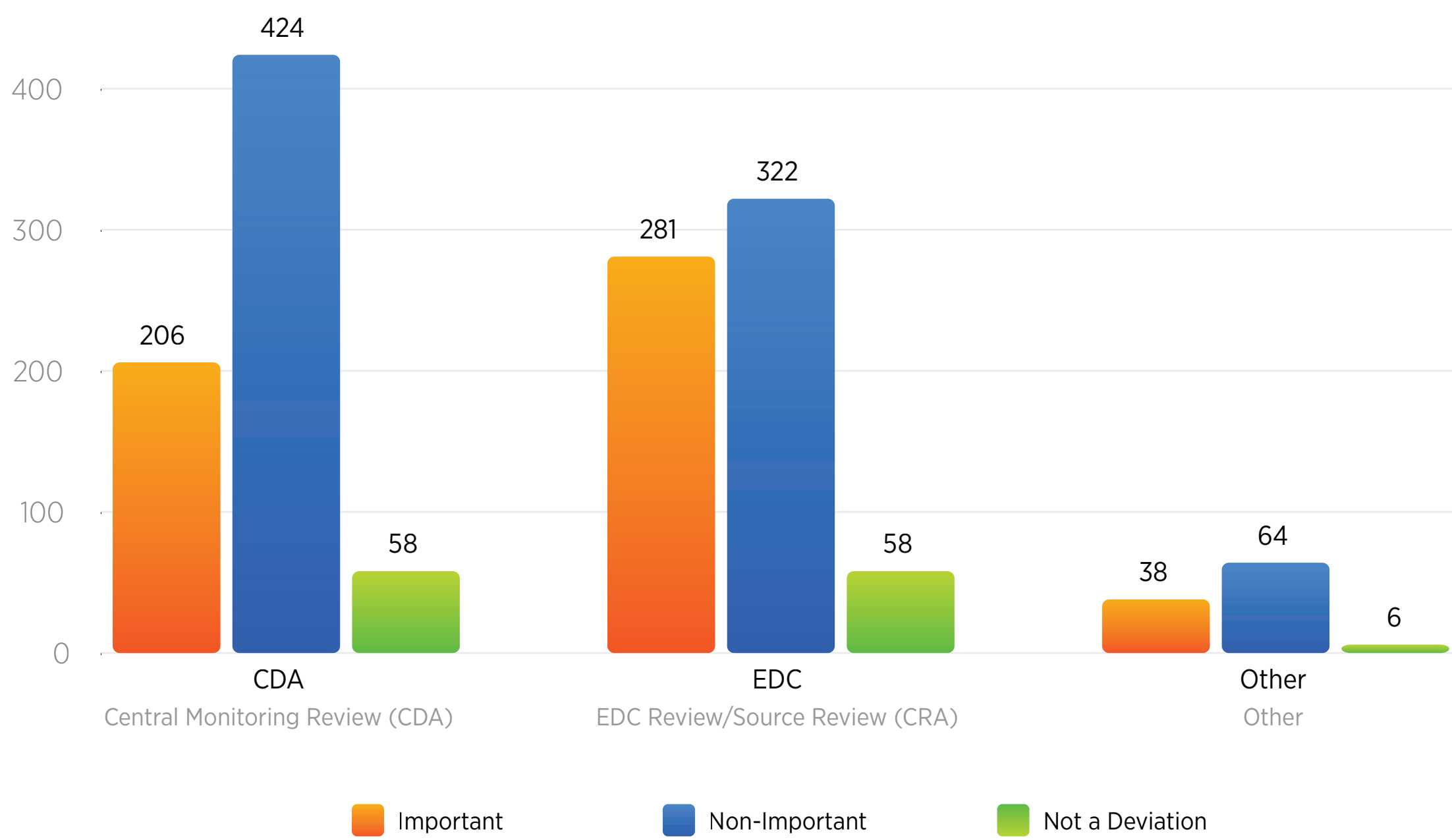
Key Findings

Central Monitoring Enables Earlier Risk Detection

- Faster identification across both Important and Non-Important PDs
- Central monitoring accounted for meaningful % of total PD detection
- Earlier visibility enabled more timely follow-up, targeted site engagement, and more efficeient deployment of on-site CRA activities

- 34% Faster** Overall PD detection with central monitoring
- 20% Faster** Detection of Important PD's with central monitoring
- 46% Faster** Detection of Non-Important PD's with central monitoring

Count of PD by Source



Key Takeaway

Advancing RBQM Maturity

RBQM metrics provide measurable evidence of impact, showing how central monitoring enables earlier risk identification within aligned processes.