CASE STUDY

BUSINESS PROCESS MANAGEMENT – OPTIMIZING RISK BASED MONITORING (RBM) PROCESS AND ACTIVITY MANAGEMENT

BUSINESS CHALLENGES

ArborSys consultants worked side-by-side with the clinical operations and technology associates of a global pharmaceutical company on a multi-year initiative to improve business process performance and cycle times across a large number of end-to-end business processes. The team identified a number of Risk-Based Monitoring (RBM) projects. The initial project selected was a dashboard to use for risk-scoring and forecasting of onsite monitoring visits. The objective was to deliver an automated tool for risk analysis and dynamic adaptive response.

THE ARBORSYS SOLUTION

The RBM Project Team focused on building quality into the process from the very beginning. Business process experts were gathered from across the organization. Using ArborSys' structured approach, the existing processes were documented and new streamlined, harmonized processes were developed.

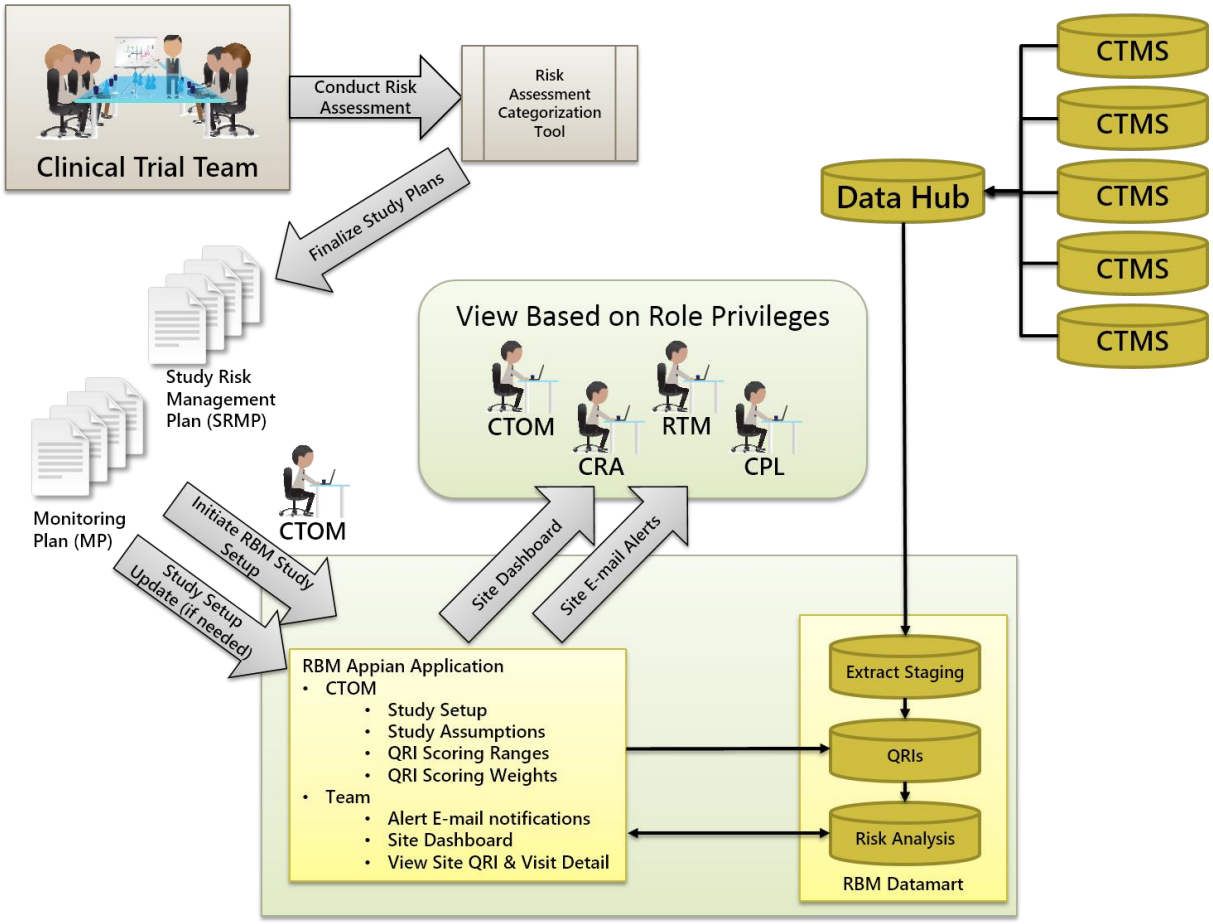
Utilizing the client's BPM software, Appian, team members were able to quickly adopt new automated routines by using the RBM Dashboard. The solution used automated risk scoring to predict the need for on-site monitoring visits, and to identify the risks that need to be addressed while monitoring a site. The initial implementation included nine Quality Risk Indicators (QRIs) for the purpose of risk identification, reporting, and notification.

The dashboard incorporated functionality matching current RBM methodology as outlined by the FDA. This allowed the user to:

- Using objective system data, provide output that determines the need for increased/decreased oversight and potentially for increased/decreased source data verification (SDV) or source data review (SDR) at a site
- Establish study protocol-specific QRI parameters and limits

- View study- and time-specific site risk scores
- View specific risk indicators at the site level
- Transmit system-generated notifications when risk indicators change
- Predict monitoring visit need based on outstanding SDV workload
- Generate site-status reports

The diagram below represents the long-term vision of the RBM application.



VALUE DELIVERED

The benefits of the RBM application included:

- Provided consistent definition of meaningful, standard study risks that were applicable across all studies
- Provided a single source of aggregated system data to project teams
- Identified early quality signals that may require specific action
- Improved efficiency, by accelerating the notification of increasing risk, especially on critical data
- Provided justification for onsite visit frequency

- Refocused monitoring efforts on protocol compliance
- Updated the client's best practices by leveraging advanced technology
- Supported continued relationship management by "real-time, data driven" follow up
- Prevented regression to legacy risk assessment practices
- Proved adaptable to changing business needs/roles

Major business goals achieved were:

- Improved technology platform delivering efficient data collection, transformation, and reporting
- Reduced risk of regulatory compliance issues
- Facilitated collaboration with external partners
- Improved investigator selection, monitoring, and relationships
- Improved flexibility, speed, and productivity
- Provided easier and faster access to information