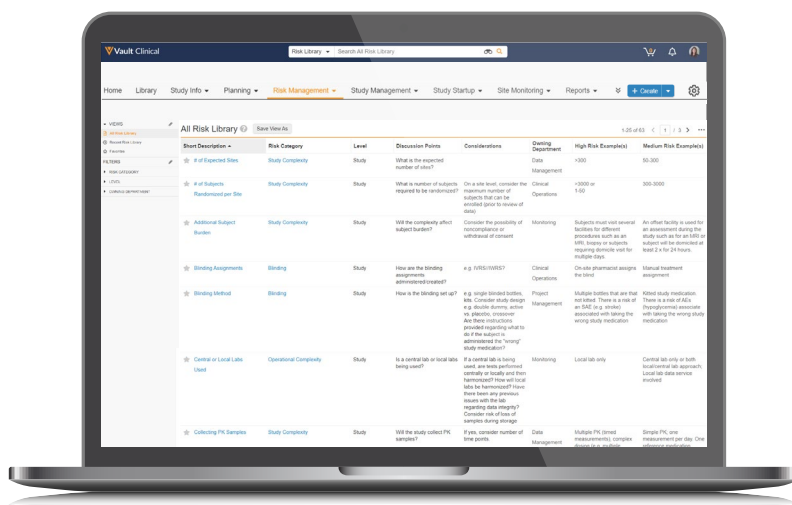


# Veeva CTMS

## Risk-based Quality Management

With a renewed focus on risk-based approaches to clinical trial management, regulators are increasingly emphasizing critical data and processes, and encouraging extended use of centralized monitoring to improve patient safety and trial quality.

Risk-based quality management (RBQM) is Veeva's flexible approach to clinical risk management that applies to all aspects of a study. Our solution enables sponsors and contract research organizations (CROs) to assess and mitigate risks at the study, country, and site levels, with configurable workflows embedded directly within Veeva CTMS and unified with Veeva eTMF. With a seamless user experience and the ability to track and manage issues, companies can decrease site monitoring costs and improve study oversight.



### Benefits

- **Improve Data Quality.** Allocate valuable resources to critical data review and monitoring sites that need the most attention.
- **Reduce Operational Risk.** Identify timeline and execution risk, then take corrective actions to keep trials on track.
- **Increase Efficiency.** Assess, evaluate, mitigate, and remediate risks within Veeva CTMS for true closed-loop issue management capabilities.

## Risk Library

Centralize risks and perform holistic cross-functional reviews by creating and managing risks in the risk library. Import risks to your library as a starting point, then reuse them across studies using risk templates.

## Critical Data and Processes

Define data points and processes that are critical to study execution, apply to study risks, assess the impact on downstream activities, and monitor throughout the trial.

## Risk Assessment Templates

Collaborate with study teams, mitigation owners, data management, stats, and other functions to create risk assessment templates for specific phases or therapeutic areas that can be used across studies.

## Study Risk Assessments

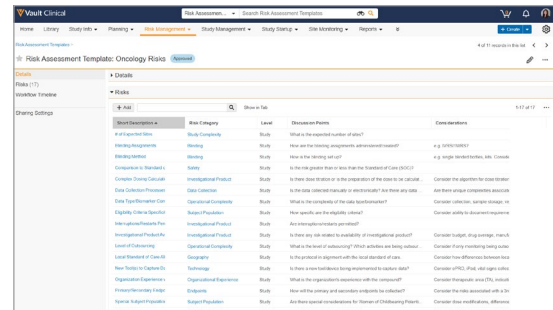
Add risks from the library to study risk assessments to create study-specific risks that can be modified, scored, reviewed, and approved. Veeva CTMS calculates the risk score based on impact, probability, and detectability, and automatically generates a risk assessment document that is classified and filed in Veeva eTMF. All changes are tracked through periodic review for a complete audit trail.

## Mitigations

Manage all of the actions taken to prevent a risk from occurring in the risk mitigation library. Relate them to risks in your risk library or create study-specific mitigations. Determine if mitigation types require action item follow-ups or tracking only, and close the loop by assessing if items are resolved.

## Reports and Dashboards

Organize, analyze, and share data with interactive reports and dashboards. Get visibility that drives action by tracking the riskiest sites and studies, identifying the most problematic risks across studies, and more.



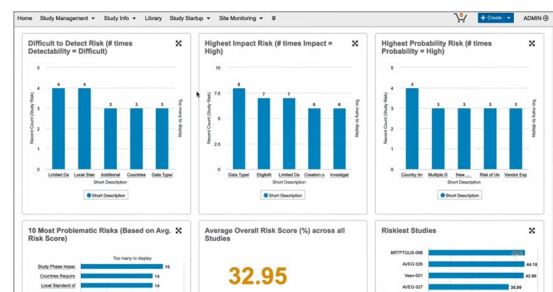
### Risk Assessment Templates

Risk Category	Impact	Probability	Detectability	Risk Score	Risk Symbol	Level	Discussion Points
Study Assignments	High	Medium	Average	12	Red Circle	Study	How are the training assignments administered?
Blinding Method	High	Medium	Easy	8	Yellow Triangle	Study	How is the blinding set up?
Center or Local Labs Used	Operational Complexity	Low	Easy	3	Green Checkmark	Study	Is a central lab or local lab being used?
Comparative Data Availability	Operational Complexity	High	Easy	6	Yellow Triangle	Study	Is the comparative data or comparison available in the study?
Complex Study Calculations	Investigational Product	High	Easy	9	Yellow Triangle	Study	Is there data that is in the proportion of the data to be collected?
Complex Study Life	Supply Chain	Low	Easy	1	Green Checkmark	Study	What is the known status of the component?
Complex Study for Study	Geography	Low	Easy	2	Green Checkmark	Study	Are there requirements for the program by specific countries?
Country Regulatory Requirements	Geography	High	Medium	8	Yellow Triangle	Study	Does the country have issues with implementation of trial or at all?
Country Regulatory Requirements	Geography	High	Difficult	10	Yellow Triangle	Study	Are there countries that are restricted from participation?
Country Specific Regulatory Requirements	Geography	High	Easy	3	Green Checkmark	Study	Are there country specific risks to ECRS approval, recruitment, or the trial?
Creation of Study of Co-Use	Blinding	High	Easy	6	Yellow Triangle	Study	Is the blinding or control on site?

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### Mitigations



### Reports and Dashboards