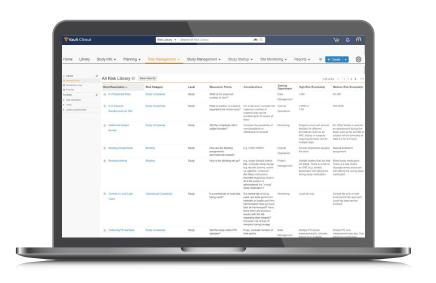
Veeva Vault CTMS

Risk-based Study 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 study management (RBSM) 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 Vault CTMS and unified with Vault 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 Vault 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. Vault CTMS calculates the risk score based on impact, probability, and detectability, and automatically generates a risk assessment document that is classified and filed in Vault 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 followups 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.

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	Comparison to Standard c	Salary	Study	Is the rok greater than or less than the Standard of Care (SOC/7									
	Complex Dosing Calculati	Investigational Product	Study	Is there dose structor or is the preparation of the dose to be calculat .	Consider the algorithm for dose titration								
	Data Collection Processes	Case Catection	Study	Is the data collected manually or electronically? Are there any data	Are there unique compresities associate								
	Data Type Biomarker Con	Operational Complexity	Naty	What is the complexity of the Gala type/comarker?	Consider collection, sample slokage, vit.								
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	Interruptions/Restarts Per-	Investigational Product	Study	Are interruptional-estarts permitted?									
	Investigational Product Av	Investigational Product	Study	Is there any tak related to evaluability of investigational product?	Consider budget, drug overage, manufe								
	Level of Cutsourcing	Operational Complexity	Study	What is the level of autocurcing? Which activities are being outpour .	Consider if only monitoring being outso								
	Local Standard of Care-RI	Geography	Study	Is the protocol in alignment with the local standard of care.	Consider how differences between loca								
	New Tool(s) to Capture Do	Technology	Study	Is there a new toxil device being implemented to capture data?	Consider ePRD, iPod, vital signs collect								
	Organization Experience v	Operational Experience	Staty	What is the organization's experience with the compound?	Consider therapeutic area (TR), indicati								
	Prmary/Secondary Endpc	Endpoints	Study	How will the primary and secondary endpoints be collected?	Consider the risks associated with a 3x								
	Special Subject Population	Subject Pepulation		Are there special considerations for 70mm of Childbearing Polanti.	Consider data modifications difference								



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Short Description +	Risk Category	Impact	Probability	Ostectabil	Risk Score	Risk Symbol	Level	Discussion Points
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Elinding Method	Binding	High	Medium	Easy			Study	How is the blinding set up?
Central or Local Labs Used	Operational Complexity	Low	High	Easy	3	~	Study	is a central lab or local labs being used?
Comparator/Rescue Drug Availability	Geography			Easy	0	-	Study	Is the background/rescue comparator medication available in L
Complex Dosing Calculations	Investigational Product	High	High	Easy	9		Study	is there dose titration or is the preparation of the dose to be cal
Compound Shelf-Life	Supply Chain	Low	Low	Easy	1	~	Study	What is the known shelf-life of the compound?
Countries Required for Study	Geography	Low	Low	Average	2	~	Study	Are there requirements for this program by specific countries?
Country Import/Export Restrictions	Geography	Med	Nedium	Average			Study	Does the country have issues with importisipant of blood or ot
Country Restrictions	Geography	Med	High	Difficult	58	•	Study	Are there countries that are restricted from participation?
Country-Specific Regulatory Requirements	Geography	High	Low	Easy	3	~	Study	Are there country specific risks to EC/HA approval, recruitment
Creation of Blinded IP On-Site	Binding				0	-	Staty	is the blinded IP created on-site?



Mitigations

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