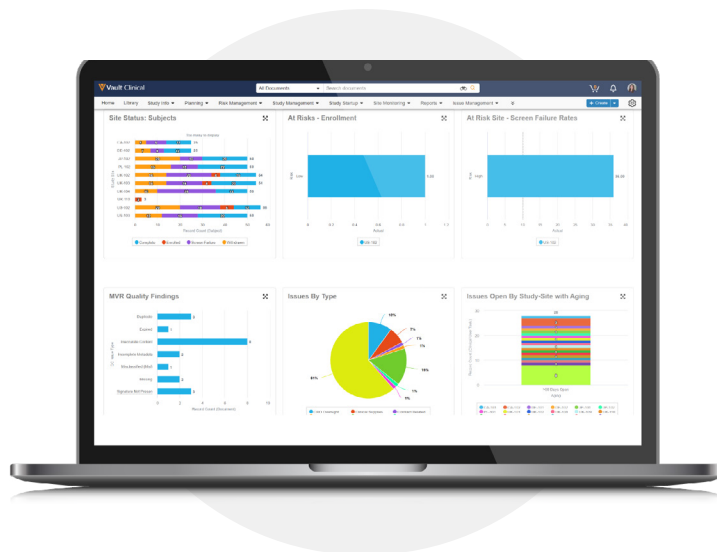


Veeva CTMS for Study Oversight in Outsourced Clinical Trials

Sponsors that delegate clinical trial activity to contract research organizations (CROs) have a regulatory responsibility to ensure patient safety, CRO compliance with standard operating procedures, data quality, and trial integrity. Regulations require sponsors to maintain oversight throughout the course of a study – and inspectors expect to see evidence and documentation of proper study oversight.

Yet many sponsors struggle to manage their trials in an outsourced model because they lack the mechanisms to perform oversight. Manual inconsistent reports in different formats from multiple CROs are ineffective and not timely, hindering study visibility.

Veeva CTMS is a modern cloud application that provides the data, documentation, and visibility to drive trial performance. From actionable insights to closed-loop issue management and protocol deviation triage, Veeva CTMS enables effective study oversight in outsourced clinical trials.



Benefits



Fewer inspection findings

Better data and documentation provide evidence of oversight, improving regulatory compliance.



Faster time to market

Speed trial execution by proactively identifying issues, managing risks, and mitigating timeline slippages.



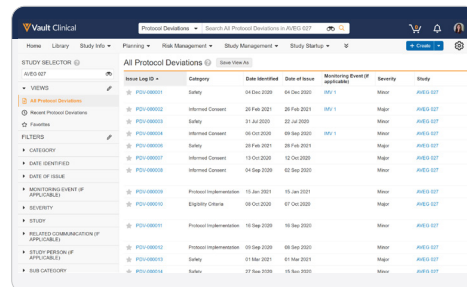
Stronger engagement with CROs

Actively monitor trial and CRO performance to improve collaboration and inform decision-making. Get visibility to CRO adherence to service and operational level agreements to strengthen contract negotiations that can result in cost savings that are reinvested back into the business.

Features

Controlled Activity: Closed-Loop Issue Management

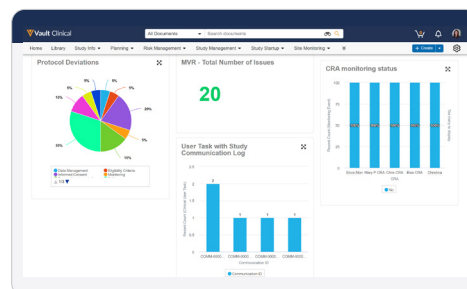
Veeva CTMS provides full lifecycle issue management, allowing sponsors and CROs to work together to drive towards resolution. Capture, create, and manage protocol deviations, clinical tasks, and follow-up items in one system for full visibility and transparency across study partners. Additionally, communication logs, audit trails, and visibility to document changes provide evidence of reviews and monitoring oversight for complete regulatory compliance.



Study ID	Category	Date Identified	Date of Issue	Monitoring Event ID	Severity	Study
PSV-00001	Safety	05-Jun-2020	05-Jun-2021	DEV-1	Minor	ABIS-027
PSV-00002	Informed Consent	20-Feb-2021	20-Feb-2021	DEV-1	Major	ABIS-027
PSV-00003	Safety	17-Jul-2020	22-Jul-2020		Minor	ABIS-027
PSV-00004	Informed Consent	06-Oct-2020	06-Sep-2021	DEV-1	Minor	ABIS-027
PSV-00004	Safety	20-Feb-2021	20-Feb-2021		Major	ABIS-027
PSV-00007	Informed Consent	19-Oct-2020	12-Dec-2020		Major	ABIS-027
PSV-00008	Informed Consent	09-Sep-2020	02-Sep-2020		Minor	ABIS-027
PSV-00009	Protocol Implementation	15-Jun-2020	15-Jun-2021		Minor	ABIS-027
PSV-00010	Eligibility Criteria	09-Jun-2020	07-Oct-2020		Major	ABIS-027
PSV-00011	Protocol Implementation	10-Sep-2020	10-Sep-2020		Minor	ABIS-027
PSV-00012	Protocol Implementation	10-Sep-2020	08-Sep-2021		Minor	ABIS-027
PSV-00013	Safety	01-May-2021	01-May-2021		Major	ABIS-027
PSV-00014	Safety	17-Jun-2020	15-Nov-2020		Minor	ABIS-027

Visibility: Real-Time Reports and Dashboards

Operational data is presented in a useful, actionable manner that allows sponsors to drill down to the details. Reporting insights prompt activity on issues and tasks, while role-specific dashboards guide activity by study, program, country, and site. Actively monitor study performance by tracking study milestones, enrollment figures, and key performance/risk indicators.



Collaboration: CRO Integrations

Sponsors and CROs can collaborate and transfer data easily into Veeva CTMS through manual and automated methods. Access multiple data domains, such as patient data, milestones, trial timelines, and issues, for a comprehensive view to keep studies on track. Data exchange from CRO applications to Veeva CTMS has never been easier.

Sample KPIs and KRIs

- Number of serious adverse events by site
- Patient discontinues and withdrawals
- Missing informed consent forms
- Protocol deviations by site and study
- Time to issue resolution
- Monitoring visit report quality findings
- Unresolved follow-up items over time

Engagement: CRO Performance

Monitoring is one of the most costly line items in a study budget, and measuring CRO performance to service and operational level agreements can surface insights that strengthen contract negotiations. Quantifying adherence to SLAs and OLAs can result in favorable negotiations and cost savings that are reinvested back into research and development.

Useful Metrics to Track CRO Performance

- Time to query resolution
- Outstanding queries
- Recruitment plan vs. actual
- % of low-enrolling/no-enrolling sites
- Monitoring timeline adherence