

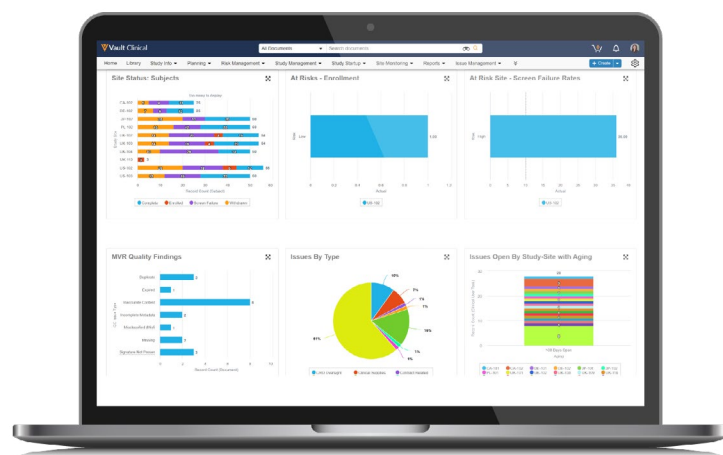
Veeva Vault CTMS

Veeva Vault 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 Vault 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, Vault 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

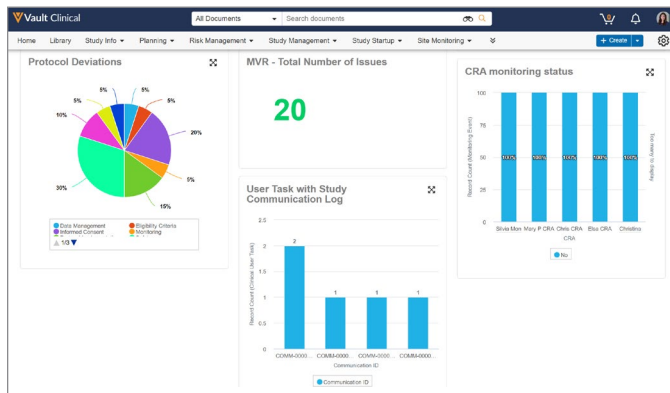
Controlled Activity: Closed-Loop Issue Management

Vault 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.

Issue Log ID	Category	Date Identified	Date of Issue	Monitoring Event (if applicable)	Severity	Study
PDV-000001	Safety	04 Dec 2020	04 Dec 2020	IMV 1	Minor	AVEG 027
PDV-000002	Informed Consent	26 Feb 2021	26 Feb 2021	IMV 1	Major	AVEG 027
PDV-000003	Safety	31 Jul 2020	22 Jul 2020		Minor	AVEG 027
PDV-000004	Informed Consent	06 Oct 2020	09 Sep 2020	IMV 1	Minor	AVEG 027
PDV-000006	Safety	28 Feb 2021	28 Feb 2021		Major	AVEG 027
PDV-000007	Informed Consent	13 Oct 2020	12 Oct 2020		Major	AVEG 027
PDV-000008	Informed Consent	04 Sep 2020	02 Sep 2020		Minor	AVEG 027
PDV-000009	Protocol Implementation	15 Jan 2021	15 Jan 2021		Minor	AVEG 027
PDV-000010	Eligibility Criteria	08 Oct 2020	07 Oct 2020		Major	AVEG 027
PDV-000011	Protocol Implementation	16 Sep 2020	16 Sep 2020		Minor	AVEG 027
PDV-000012	Protocol Implementation	09 Sep 2020	08 Sep 2020		Minor	AVEG 027
PDV-000013	Safety	01 Mar 2021	01 Mar 2021		Major	AVEG 027
PDV-000014	Safety	27 Sep 2020	15 Sep 2020		Minor	AVEG 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.



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

Collaboration: CRO Integrations

Sponsors and CROs can collaborate and transfer data easily into Vault 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 Vault CTMS has never been easier.

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