Veeva Vault CTMS

Veeva Vault CTMS is the only modern cloud application that makes it easy to unify clinical information and processes, streamline trial management, and gain complete visibility across the trial portfolio.

Study teams can manage the entire end-to-end clinical trial process and gain a global view into tasks in one unified and secure system. With simple navigation and a single source for clinical master data and study information, Vault CTMS improves operational efficiency and enables faster, higher-quality trial execution. Streamline operations with a flexible, agile solution that easily adapts to your organization's unique clinical trial needs, study designs, therapeutic areas, and business processes.

Benefits

- **Enable Faster Trials.** Easy-to-use dashboards generate real-time, actionable insights. Sponsors and CROs can quickly identify sources of delay and take corrective action to restore momentum, improving overall trial efficiency and performance.
- **Improve Decision-Making.** Strategic trial planning is easier with a full view of global operations in a single system. Get a complete and accurate view of clinical trial status to make informed decisions faster and enable proactive closed-loop issue management with real-time visibility across all studies.
- **Streamline Clinical Operations.** By providing a seamless connection to Vault Clinical Operations, organizations and their study partners have one source of truth for shared study start-up, eTMF, CTMS, and site payments data, eliminating complex integrations.

A Single Source of Truth

With Vault Clinical Operations, study teams enjoy a consistent experience with single sign-on and avoid constantly switching between multiple systems. Submit trial information and documentation once and leverage it across different systems, sites, and countries. This single source of truth improves visibility and control and accelerates trial execution.

Study Planning and Management

Plan and track study milestones across investigator-initiated studies and trial activities to optimize resources and proactively plan for events such as aligning clinical supply arrival with the site initiation visit or assessing site performance across studies. Vault CTMS enables seamless subject visit planning based on categories such as protocol, visit frequency, and procedures.

Subject Recruitment Planning

Plan the number of subjects that will be screened, enrolled, or randomized within a study and get a comprehensive view at the study, study country, and site levels. With metrics that update with actual recruitment data, you can track subject enrollment against goals to ensure studies are on time.

Site Monitoring

Manage all aspects of routine monitoring visits—pre-study, site initiation, interim monitoring, and closeout—in Vault CTMS. CRAs can view key information such as enrollment metrics and violations at-a-glance on the CRA homepage, quickly author new monitoring visit reports, and track onsite monitoring activities, all in one application.

Issue Management

Easily capture, track, and manage protocol deviations, issues, and follow-up items across all studies. Quickly identify actions needed, assess clinical task statuses, and document quality issues to enable closed-loop issue management.

Investigator Relationship Management

Empower study teams with an accurate and complete view of interactions between sponsors, CROs, investigators, and site personnel. Track site communication logs, site monitoring visits, resources assigned to sites, and more to strengthen collaboration and improve study execution.

Risk-Based Study Management

Reduce operational risk and improve data quality with configurable risk assessments. Define critical data and processes, calculate risk scores, and implement mitigations to focus and keep trials on track.

Site Payments

Unified with Vault CTMS, Vault Payments speeds payments to clinical research sites and provides financial visibility to all study partners. Designed to support complex trials, Vault Payments enables sponsors and CROs to pay sites faster and more accurately.

Study Oversight

Monitor study performance, report on the progression of subjects throughout the study, track CRO activity, and maintain communication logs to help ensure regulatory compliance with ICH/GCP guidelines. CRAs can also capture and track protocol deviations for effective issue management.

Interactive Dashboards and Reports

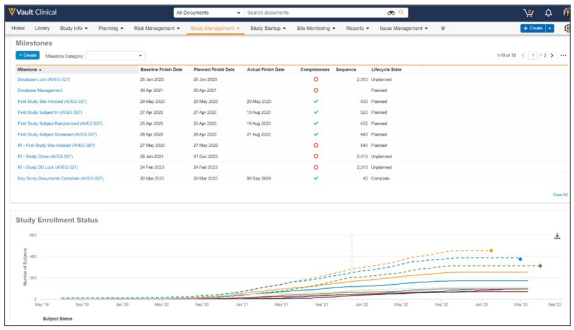
Create reports that show real-time operational metrics, documentation, and information by study, country, investigator, site activation status, and more. Study teams can take immediate action directly from dashboards, eliminating bottlenecks and increasing efficiency.

Vault Clinical Operations to CDMS Connection

Eliminate duplicate data entry and transcription errors and provide real-time visibility into enrollment status at every site. Study managers and CRAs can move seamlessly from subjects or subject visits in Vault CTMS to the applicable events and forms in Vault EDC without a separate login.

Vault Clinical Operations to Medical CRM Connection

Improve coordination, efficiency, and transparency between study teams in Vault Clinical and medical science liaisons (MSLs) in Medical CRM by transferring healthcare provider (HCP)-related activities.



Vault Clinical Operations

Vault Clinical Operations is the only solution that unifies eTMF, CTMS, site payments, site document exchange, study start-up, and study training management on a single cloud platform to accelerate trial execution, deliver real-time visibility, and improve collaboration across sponsors, sites, and CROs.