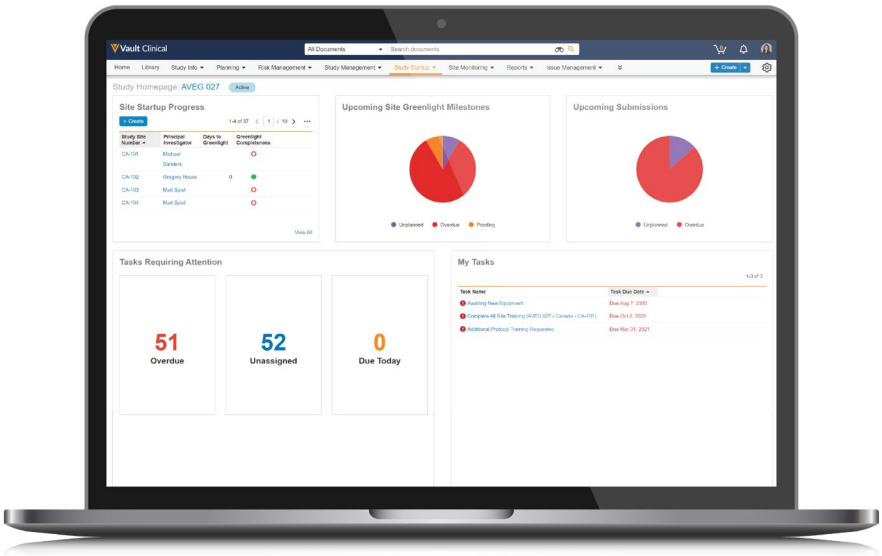
Veeva Vault Study Startup

Veeva Vault Study Startup accelerates time to site activation by connecting global teams and enabling best practices for managing country and site start-up processes.

Because study start-up documentation and data (including milestone information, baseline, projected, and actual dates) are managed in a single system, sponsors and CROs have early visibility to bottlenecks associated with events on the critical path to activation. As a result, resources can be more efficiently allocated and adjusted based on start-up progress.



Benefits

- **Speed study start-up.** Streamline end-to-end study start-up processes - from site identification to site greenlight - to accelerate time to site activation.
- **Make better, more informed decisions.** Actively monitor and track site activation progress with real-time dashboards and reports.
- **Enable effective collaboration.** Achieve greater alignment across study partners through seamless exchange of start-up content and information.

Key Features

Site Identification, Feasibility, and Selection

Easily collect investigator and facility data to make better decisions about sites that should be qualified. Distribute feasibility surveys automatically to qualifying sites for easy completion and tracking. Site selection workflows automatically trigger downstream activation activities for seamless start-up management and visibility. Key metrics and dates are tracked automatically by the system to assist with future planning and increase speed to study start-up.

Study Startup Homepage

Prioritize and manage critical tasks and milestones, including high-priority, overdue, and at-risk activities, across multiple studies through a visually intuitive homepage. Start-up specialists and managers get a quick snapshot of start-up progress, can drill down into underlying details, and take immediate action directly from the homepage.

Country Intelligence

With more than 45 built-in country workflows for document types, milestones, and dependencies that match global regulatory requirements, study start-up teams can easily and confidently navigate complex country regulations.

Study Milestones

Activities and documents required for site activation are linked to study milestones, defining the critical path to open a country and get every site to first subject, first visit faster. Measure cycle times between milestones to identify bottlenecks and areas for improvement.

Global Workflows

Study start-up specialists get a complete view of overall progress across countries, including a full list of sites and expected documents to easily identify any blockers to a site's greenlight. Workflows for submission-related milestones ensure completeness before handoff to regulatory groups.

Contract and Budget Lifecycles

Collaborate directly with investigators and legal teams to streamline site contract and budget negotiation. Guided workflows support contract review and approval with investigator sites, while security controls ensure only delegated site personnel have access. Vault Study Startup also calculates key metrics and cycle times to monitor timeliness of negotiations, assisting with better planning and faster negotiations in future studies.

Unified Clinical Operations

Vault Study Startup seamlessly shares start-up documentation, workflows, and data with Vault eTMF and Vault CTMS without complex integrations. Start-up information is leveraged across applications – from milestones and tasks that automatically populate in Vault CTMS for greater visibility to auto-filing of start-up content in Vault eTMF. This single source of truth improves visibility and control and increases clinical development efficiency.

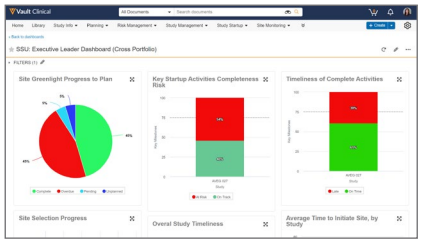


Figure 1:
Cross-portfolio executive dashboard

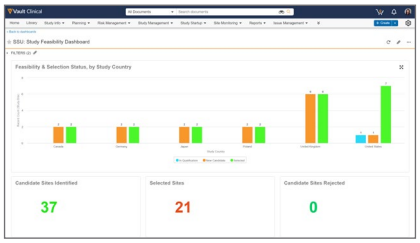


Figure 2:
Feasibility survey metrics and tracking

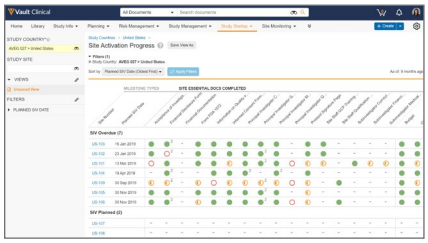


Figure 3:
Site activation progress

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.