

PRODUCT SHEET

Vault Clinical Operations

Vault Clinical Operations unifies clinical systems and processes on a single cloud platform to enable end-to-end trial management.

Clinical Operation applications share a common data model, which allows for the consolidation of clinical operations applications in one Vault.

Vault eTMF is the leading trial master file application used to ensure the quality, timeliness, and completeness of a TMF.

Vault CTMS is an enterprise trial management system that provides end-to-end study management and monitoring capabilities.

Vault Payments manages payments to research sites and tracks study budgets.

Veeva Site Connect allows sponsors and research sites to collaborate on a trial by automating the flow of information to and from sites during startup, execution, and closeout.

Vault Study Startup manages the start-up activities of a trial, including feasibility, qualification, and activation of research sites.

Vault Study Training manages GCP and study-specific training for research sites, CROs, and sponsor personnel.

PRODUCT	ANNOUNCED	STATUS	CUSTOMERS
Vault eTMF	2012	Very Mature	100+
Vault CTMS	2016	Mature	100+
Vault Payments	2020	Early	11–50
Veeva Site Connect	2020	Early	11–50
Vault Study Startup	2015	Mature	11–50
Vault Study Training	2022	Early	1–10

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Vault eTMF

eTMF is the leading trial master file application used to ensure the quality, timeliness, and completeness of a TMF. It provides full enterprise content management capabilities for upload, version control, QC/approval, and real-time co-authoring with Microsoft Office for study documents such as consent forms. eTMF is highly efficient and performant and supports global outsourcing.

Completeness and timeliness are managed through Expected Document Lists (EDLs). Content files are auto-classified through the TMF Bot, and classified content is matched automatically to EDLs.

The TMF Transfer feature simplifies exchange between sponsors and CROs by sending completed TMFs at study close.

Announced	2012
Status	Very Mature
Customer type	Enterprise Pharma, Biotech, CRO, MedTech, Consumer Health
Customers	100+
Platform	Veeva Vault
Integrations	Lives with CTMS, Study Startup, Site Connect Connected with Study Training, Submissions

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Vault CTMS

CTMS is an enterprise trial management system that provides end-to-end study management and monitoring capabilities for insourced and outsourced trials.

Dashboards and reports track key indicators, including enrollment and milestones, with drill-down to take action. Monitoring visit reports support automation and dynamic question branching. Trip reports are automatically filed within eTMF. Issues and Protocol Deviations are logged as needed and routed through resolution workflows to ensure closure.

CTMS is connected with EDC to support enrollment, monitoring, payments, and navigation to casebooks directly from within CTMS. Investigator interactions synchronize with CRM for a 360-view.

Announced	2016
Status	Mature
Customer type	Enterprise Pharma, Biotech, CRO, MedTech, Consumer Health
Customers	100+
Platform	Veeva Vault
Integrations	Lives with eTMF, Study Startup, Payments, Site Connect Connected with EDC, Study Training, Safety, Regulatory, CRM

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Vault Payments

Payments manages reimbursements to research sites and tracks study budgets.

Payment specialists define fee schedules to track payable activities such as visits and procedures. Advanced features such as advances, holdbacks, limits, invoices, and split payments are supported. Payment requests automatically generate as payable activities, which are tracked to completeness to ensure timely payment.

Payments is usually integrated with an accounts payable system for funds transfer.

Announced	2020
Status	Early
Customer type	Enterprise Pharma, Biotech, CRO, MedTech
Customers	11–50
Platform	Veeva Vault
Integrations	Requires CTMS Lives with CTMS, eTMF, Site Connect Connected with EDC

PRODUCT SHEET

Veeva Site Connect

Site Connect allows sponsors and research sites to collaborate on a trial by automating the flow of information to and from sites during startup, execution, and closeout.

Information flow includes protocols, essential document packages, safety reports, and payment letters. Required media is sent on closeout, including completed CRFs. Information sent and received is automatically filed in eTMF.

Research sites manage tasks and documents using Veeva SiteVault, a free application for sites that allows for efficient cross-sponsor collaboration.

Announced	2020
Status	Early
Customer type	Enterprise Pharma, Biotech, CRO, MedTech
Customers	11–50
Platform	Veeva Vault
Integrations	Requires eTMF Lives with eTMF, CTMS, Study Startup, Payments

PRODUCT SHEET

Vault Study Startup

Study Startup manages the start-up activities of a trial, including feasibility, qualification, and activation of research sites.

Feasibility surveys are sent to research sites during the site selection phase. Sites are automatically scored based on their response, and those selected are routed into the site activation process.

Study Startup drives site activation through standard tasks and milestones. These are controlled through provided and flexible country intelligence templates that specify the processes and documentation required before activating a site.

Information is collected, tracked, and presented in dashboard views to deliver visibility of start-up progress and timelines.

Announced	2015
Status	Mature
Customer type	Enterprise Pharma, CRO
Customers	11–50
Platform	Veeva Vault
Integrations	Requires eTMF Lives with CTMS, eTMF, Site Connect

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Vault Study Training

Study Training manages GCP and study-specific training for research sites, CROs, and sponsor personnel. It provides document, video, and SCORM/AICC training, in addition to quizzes and classroom capabilities based on curricula and training requirements.

Teams can create a protocol-specific training curriculum, which automatically assigns training based on a user's role and location. Completed training is documented automatically in an inspection-ready format for study teams and CRAs to leverage.

Study Training connects to eTMF to eliminate the need to manually capture study and site information.

Announced	2022
Status	Early
Customer type	Enterprise Pharma, Biotech, CRO, MedTech
Customers	1–10
Platform	Veeva Vault
Integrations	Requires eTMF Connected with eTMF, CTMS