

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 Operations 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.

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

Veeva RTSM is used by sponsors, CROs, and sites on clinical trials to randomize patients and manage trial supplies.

Veeva Site Connect provides one application for sites and sponsors to work together. It simplifies the flow of information during start-up, execution, and closeout.

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

Vault Disclosures manages the sharing of study registrations and results disclosures with public registries.

| PRODUCT | ANNOUNCED | STATUS | CUSTOMERS |
|-----------------------------|-----------|-------------|-----------|
| Vault eTMF | 2012 | Very Mature | 100+ |
| Vault CTMS | 2016 | Very Mature | 100+ |
| Vault Payments | 2020 | Early | 11–50 |
| Vault Study Startup | 2015 | Mature | 11–50 |
| Veeva RTSM | 2010 | Mature | 51–100 |
| Veeva Site Connect | 2020 | Early | 11–50 |
| Vault Study Training | 2022 | Early | 11–50 |
| Vault Disclosures | 2023 | Early | 1–10 |

PRODUCT SHEET

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.

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| 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, Disclosures Connected with Study Training, Submissions, Safety |

PRODUCT SHEET

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 Transfer automates the daily transfer of data between CROs and sponsors using Vault CTMS.

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.

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

PRODUCT SHEET

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.

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

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.

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

PRODUCT SHEET

Veeva RTSM

RTSM is used by sponsors, CROs, and sites on clinical trials to randomize subjects and manage trial supplies.

Sites log in to Veeva RTSM to record screening, randomize subjects, get kit assignments, and perform emergency unblinds (as needed). RTSM ensures that sites have all the supplies needed at the right time through either basic or predictive supply algorithms. Productized connections transfer patient data to Vault EDC and screening, randomization, and visit data to Veeva CDB.

Veeva RTSM is implemented, managed, and fully supported by Veeva.

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| Announced | 2010 (acquired in 2021) |
| Status | Mature |
| Customer type | Enterprise Pharma, Biotech, Consumer Health, MedTech, CRO |
| Customers | 51–100 |
| Platform | Application-specific |
| Integrations | Connected with EDC, CDB, CTMS |

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 start-up, execution, and closeout.

Information flow includes protocols, essential document packages, study communications, 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, documents, and data in Site Connect. Optionally, sites can connect their SiteVault for enhanced functionality.

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| 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 Connects with SiteVault (optionally) |

PRODUCT SHEET

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.

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| Announced | 2022 |
| Status | Early |
| Customer type | Enterprise Pharma, Biotech, CRO, MedTech |
| Customers | 11–50 |
| Platform | Veeva Vault |
| Integrations | Requires eTMF Connected with eTMF, CTMS, Study Startup |

PRODUCT SHEET

Vault Disclosures

Disclosures manages the sharing of study registrations and results disclosures with registries. It supports the entire process, including capture, review, workflow, approval, reporting, and XML generation and submission.

Pre-configured registry rules make it easy for users to comply with regulatory requirements. Automated alerts for changes in study data and milestones keep users informed about important tasks and prompt them to take action. Automatic filing of disclosure documents in eTMF helps generate proof of submission. Reports and dashboards provide visibility into global submission status, operational progress, and key metrics.

Disclosures uses data from eTMF, CTMS, and Study Startup, eliminating third-party integrations and manual entry.

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| Announced | 2023 |
| Status | Early |
| Customer type | Enterprise Pharma, Biotech, CRO, MedTech |
| Customers | 1–10 |
| Platform | Veeva Vault |
| Integrations | Requires eTMF and CTMS Lives with eTMF, CTMS, Study Startup |