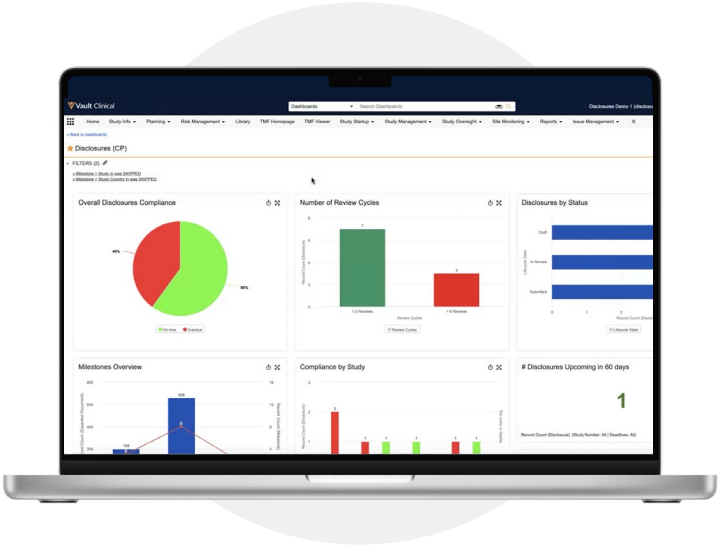
Veeva Disclosures

FEATURES BRIEF

Simple, Compliant Disclosure Submissions

In a complex clinical trial disclosure landscape, sponsors must navigate evolving regulatory requirements and manage vast amounts of data. Veeva Disclosures enables accurate submissions to avoid study delays, noncompliance penalties, and reputation harm.

Veeva Disclosures is a flexible, configurable solution that centralizes clinical trial disclosures, accelerates submissions, and ensures regulatory compliance. Manage the sharing of registration and results disclosures with registries to simplify the disclosure process from preparation to submission.



Business Benefits

Accelerate submissions.

Streamline disclosure creation and task management with pre-configured registry rules, country intelligence, and automated alerts. Reducing manual processes and inaccuracies decreases administrative burden and improves timeliness, helping sponsors meet disclosure deadlines and avoid submission delays.

Oversee compliant disclosures.

In a validated system, audit trails provide accountability and transparency by tracking disclosure creation, task execution, and identifying whether updates are user- or system-generated. Real-time data validation checks syntax and logic against registry requirements, while built-in version control ensures accurate, up-to-date documents, simplifying compliance.

Streamline efficiency and agility.

Eliminate the need for third-party integrations and reduce manual, duplicate effort by automatically pre-populating data from Veeva CTMS and generating required document lists from Veeva eTMF. Boost productivity with approval workflows and real-time document authoring, enabling seamless collaboration and efficient review of submission documents.

Features

Manage and reuse disclosures data

Centralize data and documents to simplify clinical trial disclosure management. Reduce manual entry and the need for third-party integrations with efficient data reuse by automatically pre-populating study, site, and country information from other Veeva Clinical Operations applications.

Auto-create disclosures with pre-configured registry rules

Automate disclosure creation with pre-configured rules that assess study information from ClinicalTrials.gov and CTIS. Develop a disclosure form based on registry requirements, reducing regulatory complexity.

Ensure compliant disclosures with country intelligence and validation rules

Apply country intelligence to calculate due dates and initiate workflows based on regulatory requirements. Reduce missing information and inaccuracies with real-time validation and built-in version control.

Trigger registry updates with notifications for study data changes and milestone alerts

Automated alerts notify users about changes in study data and milestone status, triggering registry updates to meet disclosure requirements.

Track global registry submissions by due date

Manage and track submissions by due date to ensure timely compliance with ClinicalTrials.gov and EU CTR. Configurable fields enable tracking of other registry submissions, providing comprehensive visibility into global disclosure status.

Streamline disclosures with guided workflows

Configure authoring, review, and approval workflows to establish clear, repeatable processes, ensuring all stakeholders are aligned with their roles and responsibilities. Automate task assignment and progress tracking to reduce manual effort and improve productivity, accuracy, and accountability.

Automate XML file generation and submission

Once protocol registration and result disclosures are complete, automatically generate an XML file and submit it directly to registries.

Leverage dashboards and reports

Create reports that show real-time operational metrics to monitor oversight and compliance. Visualize disclosure data by using configurable and pre-built dashboards to improve visibility and get actionable insights.

Unified with Veeva Clinical Operations

Pre-populate data from Veeva CTMS and apply relevant country intelligence

Reuse study, site, and country data from Veeva CTMS to pre-populate disclosure documents, reducing manual entry and inaccuracies. Automatically create disclosure activities when new study or site information is added to Veeva CTMS.

Initiate disclosure tasks based on Veeva CTMS milestone updates

Get automatic alerts for upcoming disclosure deadlines linked to Veeva CTMS milestones. Use tasks and workflows to update registries and ensure timely, compliant submissions.

Access and reuse disclosure-specific documents from Veeva eTMF

Generate a list of required disclosure documents from Veeva eTMF, then track them in Veeva Disclosures. Once new documents are approved, they are automatically filed in Veeva eTMF.

Registries Supported

- **ClinicalTrials.gov (2024)**
- **CTIS (2025)**

About Veeva Clinical Operations

Veeva Clinical Operations empowers clinical teams with a unified platform for efficient trial execution. Streamlining processes and improving data visibility from start-up through closeout accelerates timelines and enhances collaboration across sponsors, sites, and CROs.