Veeva

WHITE PAPER

# Streamlining Clinical Trial Disclosures to Manage EU CTR Complexity

Proper clinical trial disclosure is essential to complying with the European Union Clinical Trials Regulation (EU CTR) and ensuring trial success. Although the regulation aims to standardize processes and improve trial efficiency, it can also lead to increased workloads, data accuracy concerns, and inefficiencies caused by fragmented systems.

This whitepaper explores how adopting a centralized solution like Veeva Disclosures can help simplify EU CTR processes.

## The impact of EU CTR

EU CTR seeks to foster research and innovation by making it easier to conduct clinical trials in the EU and surrounding European Economic Areas (EEA). A key component of the regulation is simplifying disclosure processes by allowing sponsors to submit a single application through the Clinical Trials Information System (CTIS). Then, regulatory authorities responsible for assessing and overseeing trial conduct review the application to ensure the highest standards for participant safety and trial transparency.

### TRANSITION TO CTIS

EU CTR took effect on 31 January 2022, with a three-year transition period, repealing the Clinical Trials Directive (CTD).

**31 JAN 2022 – 30 JAN 2023**

Sponsors could apply to start a new trial in CTIS or CDT's registry, EudraCT; ongoing trials could remain in EudraCT

**31 JAN 2023 – 30 JAN 2024**

Sponsors were required to submit all new trial applications in CTIS; ongoing trials could remain in EudraCT

**31 JAN 2024 – 30 JAN 2025**

All trials must comply with EU CTR; sponsors must transition all ongoing trials to CTIS

Learn more about the **transition to CTIS**

# Challenges with EU CTR disclosure submissions

Disclosure teams transitioning to EU CTR encounter several key challenges, including:

### 01. Increased workloads

EU CTR's requirements for data privacy, collection, standardization, and data quality increase the volume of required disclosure tasks. As companies become more familiar with CTIS, they will have to meet training requirements that may result in increased administrative work to upload data and documents.

### 02. Data accuracy concerns

Without a source of truth or version-control capabilities, duplicate trial records and data discrepancies are rampant across clinical systems. These data quality and accuracy concerns force sponsors to reconcile and standardize inconsistent data formats from various registries before transitioning the data to CTIS.

### 03. Inefficiencies from fragmented systems

Most teams rely on disconnected disclosure solutions that require manual entry or integrations to aggregate information across clinical applications. When using fragmented systems, manually transferring country and site data while tracking the status of milestones and required documents leads to inconsistencies and delays. Plus, building and maintaining integrations that require duplicative effort is inefficient, labor-intensive, and complicates submission management.

**WHAT HAPPENS IF SPONSORS DON'T COMPLY WITH EU CTR?**

- → **Submission and drug approval delays**
- → **Increased costs**
- → **Penalties up to €500k per day[1]**
- → **Reputation harm**

**See the latest news and best practices on the EU CTR resource hub.**

[1] Loi relative aux essais cliniques de médicaments à usage humain, Article 45, §1

# A streamlined approach to clinical trial disclosures

Veeva Disclosures is a flexible, configurable solution that centralizes clinical trial disclosures, accelerates submissions, and ensures EU CTR compliance. The application facilitates registrations and results disclosures with CTIS, and notifies study status by country – simplifying the process from preparation to submission. By leveraging information from both clinical and regulatory systems, Veeva Disclosures eliminates the need to build and maintain third-party integrations. This ultimately accelerates trial execution and improves visibility.

## Enabling data reuse without integrations

Centralizing data in Veeva Disclosures creates a seamless flow of information across systems. Unified clinical applications enable information reuse, automatically pre-populating data from Veeva CTMS and tracking the status of documents required for submission in Veeva eTMF.

Connectivity streamlines access to product data from Veeva Regulatory Information Management (RIM), decreasing the risk of non-compliance due to redundant information. A centralized approach to disclosures provides visibility across regulatory and clinical systems and promotes collaboration to simplify end-to-end EU CTR processes.

### Unified with Veeva Clinical Operations

- Pre-populate study, country, and site data from Veeva CTMS
- Automatically file documents and leverage version control with Veeva eTMF
- Trigger EU CTR tasks from milestone updates in Veeva CTMS

### Connected with Veeva Regulatory Information Management (RIM)

- Plan, author, review, and approve regulatory documents with Veeva Submissions
- Manage, collect, and track Part I and II approvals
- Track final approvals with Veeva Registrations

### Facilitating data preparation and submission

Fast and accurate disclosure preparation and submission improves trial efficiency and effectiveness. Veeva Disclosures generates disclosures with pre-configured registry rules and applies country intelligence to calculate due dates. It automates data reuse by pre-populating information from other clinical systems and triggers registry updates based on changes in study data.

### Simplifying end-to-end clinical trial disclosure processes

Process efficiency also accelerates preparation and submission. Configurable workflows, collaborative document authoring, and user management enhance agility, while reports and dashboards deliver actionable insights. Upon finalizing Part I and II data, disclosure teams can generate CTIS documentation that flows seamlessly into Veeva Submissions, streamlining the disclosure process from start to finish.

## Overcoming EU CTR challenges with Veeva Disclosures

A complex regulatory landscape and vast amounts of data complicate clinical trial disclosures. Other point-to-point disclosure tools require manual entry and resources to build and maintain integrations. By leveraging unified and connected clinical and regulatory systems, Veeva Disclosures provides comprehensive visibility into EU CTR processes that improve compliance and accelerate drug approval timelines.

**See how unified systems simplify and centralize clinical trial disclosure management.**

**FEATURE SPOTLIGHT: DATA REUSE**

**Data reuse in unified systems**

- Data and documents pre-populate from Veeva eTMF and Veeva CTMS
- No need to build and maintain third-party integrations
- Built-in version control guarantees accuracy

**Data reuse in integrated systems**

- Manual effort to access data from other clinical operations applications
- Custom third-party integrations need to be built and maintained
- Lack of version control leads to inaccuracies and re-work

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## ABOUT US

Veeva is the global leader in cloud software for the life sciences industry. Committed to innovation, product excellence, and customer success, Veeva serves more than 1,100 customers, ranging from the world's largest biopharma companies to emerging biotechs. As a Public Benefit Corporation, Veeva is committed to balancing the interests of all stakeholders, including customers, employees, shareholders, and the industries it serves.

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