Global Medtech Company Decreases Site and Sponsor Burden with Modern Data Management

Clean, harmonized data shortens lock times, streamlines site payments, and improves compliance

Introduction

Effective clinical trial execution relies on clean, timely data from multiple sources. Medtech companies are transitioning to modern solutions to establish enduring connections between internal stakeholders and sites to speed trials and improve efficiency.

A global medical technology leader implemented Veeva Vault EDC, Vault CDB, Vault CTMS and Vault Payments across their life sciences, medical device, and interventional medicine business units to streamline data management, improve workflows, and reduce the burden on sites and internal teams. Since partnering with Veeva in 2020, the company has shifted clinical operations and data management from multiple legacy systems to the Vault Clinical Platform. They currently serve over 190 countries and have produced over 37 billion devices across their three business units.

Transitioning from multiple systems to a unified digital platform

The company's primary objectives were to standardize across business units, reduce data discrepancies and build lifecycles, and minimize manual data entry, review, and reconciliation. They took a phased approach to onboarding the three business units, with life sciences being the last to make the transition given the heavy reliance on instrument data instead of subject data.

One director of clinical data management said, "In our life sciences division the instrument data is our primary endpoint, and previously we could only capture it manually. Sites had to enter data directly into the system, which created an enormous burden on the sites and our CRAs who had to conduct a one-to-one analysis of the data."

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Director of Clinical Data Management

The company saw an opportunity to automate key steps of their clinical trial process to reduce the administrative burden on sites and CRAs. In order to address the unique challenges of capturing instrument data from sites, they identified the biggest opportunities for change across study start-up, conduct, and closeout.

Improving processes across study start-up, conduct, and close-out

Legacy systems presented barriers with data exchange between EDC and CTMS, site coordination for follow-up and fee schedules, and study tracking and reporting. These challenges were further compounded by information silos, manual processes across multiple studies, and diverse global payment requirements.

Reduced study build time by 1-2 weeks

Cut amendments from multi-week process to 1-2 days with no system downtime

Shortened end-of-study media delivery from 4+ hours to a few minutes to save 3+ weeks for a single full-time employee

Study start-up

The first objective was to standardize case report forms (CRFs) and edit checks to build a standard library and then transition to specific CRFs per business unit. To date, they have implemented 39 standardized CRFs and are able to make real-time CRF updates for future builds. By revising and standardizing CRFs, they reduced average study build times by 1-2 weeks.

Study conduct

With CRFs and associated processes in place to improve study start-up, the company was able to streamline data management during study conduct. Uploading instrument data through CDB eliminated hours of data entry and cleaning for the sites, data managers, and CRAs. They were also able to cut amendments from a multi-week process to 1-2 days with no system downtime.

Study closeout

Previously, delivering end-of-study media required a multi-step process from site documentation to acknowledgement of receipt. The company was able to transition the entire process to the Vault Clinical Platform, reducing prep time from 4+ hours down to a few minutes and saving 3+ weeks for a single full-time employee in some instances.

Impact of the revised process on an active study

The company implemented the revised processes and new workflows on a study that was key to one of their submissions in specimen management within their life sciences portfolio. The four-week study included 230 patients and was heavily reliant on instrument data. They were unable to pull data directly from one of the six instruments included in the study, which allowed them to test the automated process against manual data entry.

"To reduce manual efforts, we leveraged Vault EDC to allow sites to upload data directly from the instrument. For this specific study, this resulted in a 90% reduction in manual queries, eliminated 298 hours of data entry for the sites, and reduced source data validation and reconciliation," said another director of clinical data management. By streamlining processes and reducing manual effort, the data management team, CRAs, project managers, and sites can now allocate more time to critical study deliverables and essential details.

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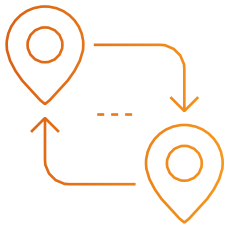
Modernizing site payments to improve connectivity between sponsors and sites

In addition to transforming clinical data processes, the company identified three core pillars of change to overcome challenges in the legacy process for site management. Their primary objectives included unifying information, improving collaboration workflows, and increasing interoperability and automation.



Leveraging the connection between Vault CTMS and Vault EDC, they have been able to automate and communicate subject activity. A senior clinical systems architecture specialist said, "data entered into Vault EDC is automatically transferred to Vault CTMS. Subjects, visits, and site payment requests are all in one location. We have screening visits linked back to source information, payable items generated for each visit, and dynamic changes automatically adjusted to payable items. This allows people to have better oversight over data changes with implications on payments, enabling our project teams to focus on the trial instead of administration. Simplicity here is our sophistication."

Key takeaways

The company embarked on this digital transformation with a long-term vision and roadmap to guide them throughout the implementation of the Vault Clinical Platform. They established clear milestones and process improvements, including:

1. **Develop a phased approach and identify priorities**
2. **Focus on data quality and integrity**
3. **Harmonize process through technology**
4. **Consider the entire clinical ecosystem – sites, patients, and sponsors**
5. **Unify and connect data and operations**

Learn more about unifying clinical data and operations leveraging the **Vault Clinical Platform**.