Global Device Company Takes Holistic Approach to Clinical Operations and Data Management with Veeva MedTech

Vault Clinical Suite transforms how clinical trials are built and managed

This global leader in medical devices selected clinical solutions from Veeva Medtech to replace a complex, multi-vendor mix of outdated applications. They chose Veeva because the Vault platform and application suites offered best-in-class capabilities across the total product lifecycle and had a proven record of customer success. The Veeva Vault platform is "new enough to bring innovation, but mature enough to be solid and reliable," said the global head of clinical R&D.

COMPANY – AT A GLANCE

- HQ: Western Europe
- Employees: 20,000+
- Products: Medical devices

Accelerating the clinical trial process

Within the clinical R&D organization, the Vault Clinical Suite has increased the efficiency and agility of the company's clinical operations and data management. According to the global head of clinical R&D, "Veeva Vault is all about speed and simplicity." By providing a single source of truth, Veeva MedTech delivers end-to-end process visibility, increases internal and external collaboration, and decreases time to market. The company considers the implementation of Veeva's clinical systems a "raving success," with nearly 100 studies managed in Vault CTMS after only six months.

One highlight of their journey is the transformation of the trial data manager's role. Vault CDMS reduced the technical expertise required to build studies by eliminating the need for custom programming. Data managers are now empowered to support trial teams by designing and building studies themselves. The company's more technical data managers were able to learn the basic rule programming in Vault EDC, and the expanded role has improved their job satisfaction and resulted in faster study builds with no extra headcount. The move has also freed database developers to focus on building standards and any complex programming tasks.

"Veeva MedTech is all about speed and simplicity."

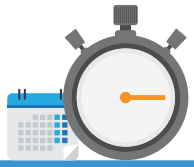
– global head of clinical R&D

Leveraging a connected platform

Vault Connections provide additional efficiencies and opportunities to automate business processes. Information from subject visits automatically transfers from Vault EDC to Vault CTMS to help populate monitoring trip reports and automate site payments. Looking ahead, automated processes will extend to sites to reduce the burden of administrative tasks and archiving paper records.

In addition to the Clinical Suite, the company implemented Veeva MedTech solutions across its quality, regulatory, and commercial functions. Deploying a unified platform across the enterprise has allowed them to streamline cross-functional business processes and improve data quality. "We have a single source of truth for all our documents," explains the manager of clinical trial document management. "The Investigator's Brochures and Clinical Study Reports are created and managed in Vault RIM and are readily available in our TMF. It makes things so much easier."

Moving forward, the company will pursue more opportunities for business transformation with new connections between Veeva applications and other systems. "We have already accomplished a tremendous amount and achieved so many milestones," says the vice president and head of clinical operations. "Going digital with Veeva is a true partnership. It is transforming the way we work in clinical and presents an enormous opportunity for the broader company."



6 months saved by implementing Veeva's out-of-the-box configuration

3 studies built by data managers within 90 days of initial training

100% of data managers prefer Veeva to previous EDC system

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– vice president and head of clinical operations

Case Study – A Focus on Clinical Data Management

By the global head of clinical data management

"We had a blank canvas to create something that enables the business to be more agile and efficient. It was the opportunity to create a masterpiece with the time pressure of a 100-meter dash. And we did it.

The CDMS implementation was very fast, we finished two months before our target. We were able to transition many of our standards into Vault EDC, which helped our trial data managers ramp quickly and begin building studies themselves. The transition was also surprisingly easy for our sites, so while we achieved faster builds, there was no regression in cycle times or data quality.

Upgrading our systems gave us an opportunity to ask: 'How can we drive maximum value to the organization while fulfilling our team members' development goals and supporting their professional growth?' We've done that with CDMS.

A good example of empowering our data managers came with Veeva's Agile Design process. Instead of writing specs in Excel and asking the study team to review those, our trial data managers start with our standards and then spec and build the studies directly in Vault EDC. Our programmers step in for the complicated rules. The study team reviews the forms in the system which is significantly faster and easier than reviewing PDFs and spreadsheets.

There is also no need for custom programming, which reduces the technical expertise needed for builds. These changes eliminated lots of manual steps plus the back and forth with developers, saving us tons of time and energy. It also contributed to a growing closeness between cross-functional teams. The CDMs know their studies and the system inside and out, which has created a more efficient team dynamic.

The biggest win for me is the difference this has made to our team. The capabilities of Vault EDC enable data managers to do more independently and at a much faster pace. When we polled them, 100% of our data managers said that they preferred working with Vault EDC over the prior system."