Global Medical Diagnostics Company Builds Clinical Center of Excellence with Veeva MedTech Solutions

Vault Clinical Suite enables greater speed, efficiency, and agility in clinical trials.

As a leading global medical device diagnostics company, clinical teams were looking to establish a Clinical Trial Center of Excellence, a far-reaching initiative that encompasses people, processes, technology, and partners. Their goal was to set the industry gold standard for the conduct of clinical diagnostics execution.

Clinical Trial Center of Excellence

Before beginning its pursuit of clinical excellence, Clinical Affairs operated on manual processes with multiple spreadsheets and information silos. To support growth, the company needed to collaborate, track, and scale trials more efficiently, while improving data quality, reporting capability, and compliance.

They selected Vault Clinical Operations and Vault CDMS from the Veeva MedTech Suite as the technology foundation for its new Clinical Trial Center of Excellence. Veeva's connected suites enabled clinical leaders to take a unified approach to clinical operations and data management. In the first phase of its implementation, they centralized the management of non-clinical study data in Vault CTMS and consolidated study documents in Vault eTMF. This has streamlined the clinical trial process and allows Clinical Affairs to make faster, more informed decisions with a comprehensive, real-time view of study status. In addition, the organization is always in "inspection-ready mode," with TMF documents at their fingertips.

Rapid Pivot to Electronic Data Capture

With Vault CTMS and Vault eTMF in place, this leading medical diagnostics company was ready to leverage more of Veeva MedTech's clinical capabilities. They wanted to build on the momentum and strong partnership to integrate the clinical data management system into the clinical affairs infrastructure. An important driver was the ability of Vault CDMS to meet their challenging data requirements, which involve merging traditional EDC data with large, complex sequencing output files.

The team accelerated its plans when they obtained an emergency use authorization (EUA) to support COVID-19 screening programs. The organization set a goal of one month to prepare a study to test the detection of the virus in nasal and saliva samples. The protocol development, database build, and study prep that normally occurs over a six-month period was completed in one month. CDMS was always on their roadmap, but because COVID came along, they needed a rapid way to build the database and get EDC live faster than ever before.

EDC Build in Four Weeks

Given the need for speed, the medical diagnostics company had Veeva build the COVID-19 study, while using the project to jumpstart internal enablement by having internal data managers shadow Veeva study designers as they configured the EDC system. Leveraging agile design innovations and CRF templates for a COVID-19 study, the study was delivered within one month—with the actual work of developing and testing the database requiring less than a week.

1 Day
Programming rules and edit checks

1 Day
UAT changes completed

1 Day
Post-production change to ID format for nasal swabs

1 Day
Extracts were configured and validated

Vault EDC allowed study designers to easily incorporate last-minute protocol changes, a critical factor in the volatile COVID environment. Because COVID changed by the day, so did their protocol. Clinical teams were constantly going back to make changes. The flexibility that Vault EDC offered and the way the teams collaborated really made it all possible.

Manual processes and spreadsheets slow trials down and weren't a viable option to support this study. However, the organization was able to complete the protocol, build the database, and get the study live in a month.

Successful Adoption and Enablement

In parallel with the COVID-19 study startup, the company ran an enablement program to develop in-house EDC skills for their many clinical trials. The clinical data team lead believes that watching and participating as Veeva built the COVID-19 casebook amplified the success of the enablement program. He reports that "learning from Veeva's experts has helped us make the most of Vault CDMS technologies and the agile design process."

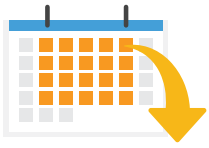
Internal teams are now using Vault EDC to quickly configure and modify study builds on their own as the organization is well positioned to deliver on evolving EDC needs.

Ready for Innovation and Growth

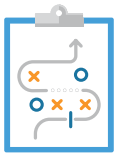
The Veeva MedTech Suite plays an integral role in helping this leading medical diagnostics company drive innovation and growth. The Vault Clinical Suite underpins the company's commitment to patient safety, quality, and data integrity. Ultimately, the ability to deploy and run clinical trials with greater speed, efficiency, and agility will help them bring new products to market faster.

Success Highlights

Faster, more efficient study management



EDC build in under four weeks



Flexibility to respond to changing EDC needs

Inspection-ready across Clinical Affairs globally