NuVasive Unifies Clinical Operations to Drive Efficiency and Ensure Compliance

NuVasive, a pioneer in minimally invasive spinal surgery, is dedicated to helping physicians reduce patient back pain and post-operative recovery time, as well as the time required for each surgical procedure. Established in 1997 and now selling in more than 50 countries, the company aspires to "change one patient's life every minute," offering a range of medical devices, biologics, and other surgical materials, as well as training and clinical education programs that leverage the knowledge of world-class surgeons.

NUVASIVE, INC.

Headquarters: San Diego

Founded: 1997

Number of Employees: 2,900

Net Sales: $1.14 billion

Solutions: Vault eTMF, Vault CTMS

As NuVasive's growth accelerated, its clinical research leaders began to realize that the company's homegrown SharePoint-based system could no longer handle the increased volume and changing nature of day-to-day demands for clinical data and documentation. "Compliance to EU MDR shifted our business as we had historically conducted our post-market studies for marketing purposes and evidence generation, rather than to meet regulatory requirements. This shift impacted the number of studies we sponsor, but also how we scrutinize all study-related activities," explains Shannon Bahn, senior manager of clinical affairs.

The gap between the company's existing system's performance and its future needs became most apparent in 2019. Shannon and a team charged with finding better alternatives took inventory of the most challenging aspects of their day-to-day, and assembled a wish list of capabilities from a new eTMF and other clinical applications that would drive efficiency. Because they had never used an eTMF or CTMS before, they weren't even sure of what they needed at first. "Once we began to compare solutions, the process became easier," Bahn says.

Document collection, tracking, and storage

The team's greatest time drain and source of risk was handling and storing medical qualification and good clinical practices (GCP) documentation. While the nature of its research programs changes continually, NuVasive tends to work regularly with a core group of surgeons and research sites. "Many of the surgeons we partner with are contributing to multiple studies, so there is duplication in the documents that we need to collect," Bahn comments.

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>
> —**Shannon Bahn**, senior manager of clinical affairs

NuVasive's team realized that relying on a manual document-collection process and fragmented document storage was inefficient and difficult to maintain. There was no easy way to keep track of surgeons' medical licenses or CVs, for example, to see when they would expire or need to be updated. GCP documentation also needed to be managed, as well as NuVasive-specific required documents, IRB approvals, and site communications. "We had trackers for everything," she recalls.

Although the process may have worked, the fact that it was handled manually increased the risk of errors. It was also highly dependent on clinical team members' knowledge and access to the document management system. "Our previous system was heavily email dependent and required that documents be checked-in prior to being visible or accessible to others. If file owners on the clinical team were sick or on vacation, efforts could come to a halt because the rest of the team couldn't access information easily," says Bahn.

Eliminating redundancy by reusing documents

The change management team agreed that any new system would have to enable them to reuse and update qualification documents. After evaluating a number of systems, they found that Veeva Vault eTMF was the only one at the time that offered that capability and was user friendly.

Another vendor promised to add document reuse to its product planning list, says Bahn, but NuVasive was initiating six clinical studies in 2020-2021, the most aggressive series of study launches the company had experienced. They needed the ability right away.

"After writing and formalizing all our trial protocols and setting up the data and documentation internally, we began to launch the studies in the fourth quarter of 2020, rolling them out individually," says Bahn. In 2021, with studies already underway, the team spent a quarter configuring the systems, setting a go-live date for implementation by October of 2021. "By the end of 2021 we had transitioned all eTMF activities for our six active studies to Vault," she says.

Since go live, NuVasive has utilized Vault eTMF and CTMS for a total of nine prospective studies, while utilizing the eTMF functionality for an additional two studies. NuVasive has been using all of the Vault platform's monitoring activities functionality since the end of 2021.

Adoption and change management

The change has gone smoothly but has involved a massive learning curve, Bahn relates. She now wishes she had taken more advantage of the application's flexibility by creating multiple custom templates right off the bat, for things like FDA-regulated, post-marketing, and retrospective studies.

Since implementing Vault eTMF and CTMS, the clinical team has been gradually adjusting to the new tools and processes. "I try not to force change, and instead, work based on the comfort level of each individual on the team, and offer to support them," Bahn comments. A year into the project, more team members have become comfortable discussing what they need and want to do with the system. Bahn continues to emphasize the importance of reporting, the utility of dashboards, and encouraging team members to start their workdays by opening Vault first, instead of the original system.

Getting people to open up about issues and their experiences with new systems is the best way to help them embrace change, as well as being owners in the solutions. Solutions that have supported the adoption include ad hoc meetings for screensharing, working groups to create and update work instructions, team office hours to create an open dialogue between teammates, and users to have a role in whether changes need to be implemented in the current system.

Reliability and built-in compliance

While team members are excited about dashboards and reporting functions, the team is still transitioning away from long-established ways of doing things, says Bahn. This is a normal reaction to any change, she adds.

"Any kind of technology change poses a challenge, as clinical teams experienced when they moved from paper-based clinical systems to electronic data capture systems (EDC). It may be more familiar to write a monitoring letter in MS Word, but it is much more efficient and reliable to have a system in place that generates that letter automatically and populates it with accurate data from other connected systems," she says.

Gaining that reliability, and ensuring regulatory compliance is well worth the effort of having the team learn and adjust to a new system.

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Automated trip reports a major help

As a project and people manager, Bahn says that moving from manual processes to using Vault eTMF and CTMS has made it much easier to get updates on how many sites each CRA is managing to understand workload and forecast site visits. "I'm a huge fan of having automated trip reports, and the fact that the eTMF pulls data directly from the EDC so that CRAs no longer have to input the data manually is a huge time saving. Documents are much easier to find, too," she says.

One year into the project, all of NuVasive's clinical studies are now supported by Veeva Vault eTMF and CTMS.

Working with Veeva on this project has been a true partnership, Bahn says, especially since the designated system owner, a member of NuVasive's programming team, has another full-time job to manage. To provide some depth to the current system owner, NuVasive has taken advantage of the Configuration training hosted by Veeva, by having a member of the clinical operations team attend the training. Ensuing the team has more depth within the team to manage the system, as well as having a point-person who can train future users and oversee processes will aid to efficiency.

For now, Bahn plans to continue exploring new facets of the Vault applications, to make sure that everyone on her team is using them in a way that meets regulatory requirements, and to help all team members become more comfortable and more efficient.

Learn more about Veeva MedTech Clinical Solutions.