Zelta

merative

Life-saving treatments reach patients faster

LivaNova accelerates clinical trial launches

A great deal of thought goes on behind the scenes before any clinical trial for a new medication or medical device can begin. As the sponsor designs a study based on an approved protocol, it must also build a database in an electronic data capture (EDC) system that houses all the critical information collected during the trial.

Because of its global reach and growth, LivaNova PLC had several EDC systems from multiple vendors to manage its clinical trials. One of its most widely used systems required programming language for the initial database design, which slowed the trial launch process considerably.

LivaNova decided to explore the EDC/CDMS marketplace for a single trial management system designed for ease of use. It also sought a solution to simplify and streamline its trial launch and management processes to help get lifesaving devices to patients sooner.

According to Jason Peters, Sr. Director, Global Data Management, LivaNova, the company sought three critical elements. "First, we wanted a system where we could ultimately build the database ourselves, in house," he states. "Second, it had to be cost competitive. And third, it had to be a system that was not only recognized in the clinical research industry as a good, solid solution but also easy to use for our clinical sites."

The company initially looked at 42 options, which it soon narrowed down to four. LivaNova provided these four companies with a mock scenario to bid on, and then narrowed the field to Merative™ and another vendor. Merative also demonstrated the endpoint adjudication module built into the Zelta, clinical trials platform. "It was just night and day difference between any other vendor that we had seen in terms of their adjudication module," says Peters. And it became a key factor in the selection process.

The team reassured Peters that LivaNova would receive personal attention directly from the Merative team. This commitment was then demonstrated as the team worked to create the right solution for LivaNova. "What we liked was that Zelta was very flexible," says Peters. "They were thinking outside the box to help us find ways to save costs as well as to ensure that we had a great product."

Speed of database built time

75%

reduction in initial study build time

Reduction in average number of errors during initial quality assessment

57%

Fewer

“For me, what’s most important is the relationship; and that’s being able to work with a vendor who’s willing to work with you.”

Jason Peters
Sr. Director, Global Data Management, LivaNova

Choosing a cloud-based platform

LivaNova signed a Cloud Services Agreement (CSA) with Merative for the Zelta clinical trials platform. The unified CDMS platform is designed for ease-of-use at all project stages—from study design to deployment to final submission of data—and for all users, including designers, principal investigators and even patients. The solution does not require programming language expertise—LivaNova can build its own database or tap into the expertise of Merative developers.

The Merative team quickly designed two new clinical studies for LivaNova; it delivered each of them in just 44 days. The second study was a complex randomized trial that "took a lot of really deep understanding, not only of what it should look like for the user, but also from a technical standpoint," according to Peters. "I was pleasantly surprised that it took such a short amount of time to accomplish the database build."

The Zelta clinical trials platform can support any clinical trial type, size or phase. Many of LivaNova's clinical trials are global in scope, with principal investigators in multiple sites.

A single user portal keeps team members on the same page, regardless of their location. The Zelta platform allows the company to automatically gather and integrate data from anywhere in the world, and builtin reporting and analytics help uncover patterns and insights from data.

Finally, even patients can benefit from LivaNova's choice of CDMS solution. The built-in ePRO module allows patients to share information with principal investigators at any time during the study, not just at scheduled visits.

LivaNova is also using the endpoint adjudication module, recognized as one of the best in class by clinical trial sponsors. Fully integrated with the solution's core EDC functionality, the module allows the user to configure the workflow, specify what information needs to be presented and to whom, and automatically compile an electronic dossier of the required endpoint details.

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Jason Peters
Sr. Director, Global Data Management, LivaNova

Gaining speed without sacrificing quality

LivaNova quickly launched the two clinical trials built by Merative using the Zelta clinical trials platform. Each study required only 44 days from final specifications to go live—approximately 25% less time than the company's experience with its previous vendor.

But speed without accuracy can be just as costly as a delayed trial. However, the two databases had an average error rate of 16 in the initial quality assessment round of user acceptance testing (UAT), compared to an average of 38 errors in the databases built by LivaNova's previous vendor, representing an almost 60% improvement in quality.

Again, Peters was impressed by the Merative team's work on the second clinical trial. "This second database was incredibly complex," he says. "It was probably one of the most complex study builds in my 20 plus years of industry experience."

The simple one-click access to a compiled dossier of all endpoint details and source document was a key feature that attracted LivaNova to Zelta. "It's elegant, it's simple and it works well," says Peters. "It has a nice workflow and doesn't require a whole lot of extra steps." The module can help reduce costs by producing fewer paper documents to track, ship and review while expediting cycle times with an online redaction tool and direct electronic collection of source documents.

While Peters lauds the technical expertise and dedication of the Merative build team, he appreciates the deepening relationship with the team and with Merative even more. "To me, the relationship that I have with the Merative team far outweighs anything that they can do technically," he says.

He has had fruitful conversations with the team regarding implementing new features in the CDMS solution. He has also had harder discussions regarding pricing where Merative and LivaNova have reached a mutual understanding. "We have the relationship to be able to have those difficult conversations, and for me to be able to express my concerns," says Peters. "A lot of vendors are not going to spend that time to work with their customers. We're a relatively small company. I may not always get what I want, but that's okay. I feel valued. I feel heard, I feel listened to, I feel appreciated."

LivaNova
Health innovation that matters

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About LivaNova PLC

LivaNova is a global medical technology and solutions company headquartered in London. Founded in 2015, the company is a recognized leader in cardiovascular solutions, including in cardiopulmonary bypass and its truly sutureless aortic valve replacement. LivaNova's approximately 4,000 employees work in more than 100 countries around the world, advancing medical technology and knowledge.

About Merative

Merative is a data, analytics and technology partner for the health industry, including providers, payers, life sciences companies and governments. With trusted technology and human expertise, Merative works with clients to drive real progress. Merative helps clients reassemble information and insights around the people they serve to improve healthcare delivery, decision making and performance. Merative, formerly IBM Watson Health, became a new standalone company as part of Francisco Partners in 2022.

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