

Using Syndicom SpineConnect to enhance patient selection, enrollment, and outcomes during a clinical trial

In January 2007, Applied Spine received permission to begin a randomized, controlled clinical study to compare the Stabilimax NZ® Dynamic Spine Stabilization System against traditional posterolateral fusion. To facilitate this multi-center study, the company turned to Syndicom, the premier developer of collaborative communities, and its widely embraced SpineConnect platform, which is currently used by over 900 spine surgeons around the world. Surgeons participating in the clinical trial use SpineConnect's TrialEdge, a unique Web-based service built on Syndicom's proven collaboration methodology, to improve their ability to identify, enroll, and retain patients. As a result, Applied Spine has seen faster patient enrollment, better trial quality, and lower costs. An added advantage has been the generation of teaching cases for educational purposes, marketing, and research, and development.

Situation

Applied Spine Technologies Inc., headquartered in New Haven, Conn., received FDA approval to begin an IDE trial on its Stabilimax NZ® device in early 2007. The multi-center, randomized, controlled clinical trial compares posterior dynamic stabilization using the Stabilimax NZ® Dynamic Spine Stabilization System to patients receiving traditional fusion stabilization to treat degenerative lumbar spinal stenosis. A total of 266 Stabilimax NZ® patients and 133 control patients across 20 different sites are to be enrolled in the trial.

Applied Spine faced a challenge familiar to that faced by other medical device companies conducting clinical trials: Because the participating investigators are spread out across 20 sites, efficient communication between the parties is problematic. Typically, Principal Investigators (PIs)¹ collect the patient data submitted by the surgeon investigators and meet one to two times a year to go through the patient cases post-operatively - a highly inefficient process that leads to reactive decisions, rather than proactive ones.

"One of the responsibilities of the PIs in any clinical trial is ensuring adherence to standardized protocols," said Dr. David Musante, an orthopaedic surgeon at

Triangle Orthopaedics in Raleigh, NC, and one of the principal investigators (PI) of the study. "As you can imagine, inclusion and exclusion criteria, strictly defined

¹The principal investigator is responsible for conducting and coordinating the overall clinical trial.

as they may seem, can be interpreted in slightly different ways based on a particular surgeon's training, location, and experience. In a typical clinical trial, the investigators meet at an annual or semi-annual meeting and review the cases postoperatively. This makes it somewhat challenging to monitor whether we are achieving reasonable uniformity in our application of the inclusion or exclusion criteria across all submitted cases."

All clinical trials always include guidelines about who can participate. Using inclusion and exclusion criteria is an important principal of medical research that helps to produce reliable results.

"Communication is exceedingly important when running a tight and compliant study," said Richard Guyer, co-founder and fellowship director of the Texas Back Institute, another principal investigator in this study. "Any ongoing lack of communication means that questions regarding protocols and patient selection are left unanswered. That means patient cases that are on the edge or fringe of the defined protocol often end up being included - which is not desirable."

For Applied Spine, the answer was clear: leverage surgeon-to-surgeon communication for better results. "Today's clinical trial landscape is littered with trials that fail to meet their planned timelines and patient accrual goals," said Thomas E. Wood, CEO of Applied Spine. "We believe that surgeon-to-surgeon communication and collaboration on a daily basis is a key driver of successful trial outcomes."

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Solution

To build the collaborative platform for its Stabilimax NZ® clinical trial, Applied Spine approached Syndicom, the developers of Syndicom SpineConnect.

“I really liked how SpineConnect had successfully built a community of spine surgeons and created an atmosphere where they could freely discuss their viewpoints –with the shared goal of improving patient outcomes,” Wood said. “We were looking for that same type of environment – one that would facilitate the communication between surgeons working on the clinical trial. In effect, we needed a surgeon education tool within the context of the Stabilimax NZ® clinical trial. One in which surgeons could get feedback not only on protocols and inclusion/exclusion criteria, but also on the actual surgery.”

Syndicom created the Stabilimax NZ® TrialEdge group, built on the SpineConnect platform that connects PIs, participating surgeons at the twenty sites, and Applied Spine representatives. HIPAA compliant preoperative images of patient cases are posted to the TrialEdge group, so that the PIs can view the cases and determine if the patient case follows the protocols of the study. The group acts as a sounding board for submitted cases – making sure that the patient fits the indications of the device. The posted cases end up serving as exemplary models for the study. The Stabilimax group has also undergone a transformation based on the growing needs of Applied Spine.

“What has really surprised us is how the site has evolved like an ecosystem to support our changing needs during the clinical trial,” Wood said. “I view it as a piece of soft clay that we can mold to fit our needs. The platform is flexible enough, so that it can meet the expanding needs of our company.”

While at the outset of the study only pre-op images were being posted for patient selection purposes, the site evolved to include post-op images that were designed to build a knowledgebase of teaching cases. Now, Applied Spine is taking it one step further by also including the previously excluded patient cases. According to Wood, “All this data is critical to our understanding of the Stabilimax NZ® device; we haven’t even scratched the

surface in terms of the Stabilimax group’s potential.”

For Musante and Guyer, the Stabilimax NZ® TrialEdge group represents a paradigm shift in how clinical trials are conducted. “This trial has been unique because it’s enabling PIs to do something we’ve never been able to do before,” said Musante. “If SpineConnect is used to its fullest potential, we now will have the ability to easily evaluate every patient case that is being submitted and how they are being treated prior to the procedure. It gives us an unprecedented amount of supervision over the study and its protocols and the opportunity to address issues in a timely fashion, which I think will result in a better overall study.”

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David Musante, MD
A Principal Investigator of the
Stabilimax NZ® Study

“What I love is the educational aspect for all the participants and the fact that it is a living process,” continued Guyer. “We become problem solvers with the other investigators, and we communicate all the time. We no longer have to wait up to a year to discuss the cases – it’s instantaneous. I love the technology, because it brings people from all over the world to the table to solve real-world problems in real time.”

Applied Spine is also leveraging the collaborative nature of the group by including Medical Metrics, a leader in medical imaging services dedicated to orthopaedic trials. By participating in the group, Medical Metrics can apply its advanced radiographic analysis software to produce an accurate real-time assessment of motion and other changes between images.

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Concludes Wood, "SpineConnect has surpassed our expectations. Not only has it improved the quality of the patients enrolled in the study, but it has become a patient education tool for the investigators in a completely non-threatening way. The result will be a superior clinical trial that meets its patient accrual and outcome goals."

Benefits

The Syndicom solution has enabled Applied Spine to run a clinical trial that is more tightly controlled resulting in a higher quality study. Investigating surgeons can proactively identify cases that strictly adhere to the protocols, provide comments, and learn from each others' experiences all in a secure, HIPAA compliant environment.

Produces a higher quality study.

Because the principal investigators of the Stabilimax NZ® trial have access to preoperative images, they can reject those that do not fit the inclusion/exclusion criteria proactively. Furthermore, the principal investigators can enforce protocols based on their interpretations, which results in a more homogenous pool of patient cases and a superior clinical trial.

Reduces trial costs through instantaneous communication.

Because SpineConnect is on the Web, investigators can receive real-time feedback on patient cases anytime of the day or night. For the first time, investigators across multiple sites can review all the trial cases in an organized, easily accessible, and thoroughly documented way to identify problems earlier and take corrective action sooner, thus reducing overall trial costs.

Builds a knowledgebase of teaching cases.

Applied Spine is able to build a central repository of cases, which investigators can use as a resource in determining whether a patient fits the trial's criteria. Pls can illustrate the types of patients they are looking for through the cases that are posted. Furthermore, because investigators contribute postoperative images as well,

companies can use these cases as teaching cases and in marketing related materials.

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*Tom Wood, CEO
Applied Spine Technologies, Inc.*

Syndicom Solutions for the Medical Device Industry

Medical device companies are under tremendous pressure to meet regulatory requirements, improve patient care, and reduce the time it takes to develop devices and take them to market. To meet this challenge, Syndicom has developed cost-effective solutions that enable medical device companies and surgeons to collaborate on education, training, research, and development to improve productivity and deliver collaborative solutions whenever and wherever they are needed. The result is enhanced productivity and improved patient outcomes.

For More Information

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