CLINICAL LEADER

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# Transforming Clinical Operations To Become A Sponsor Of Choice

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The clinical operations team at CSL Behring has come a long way in the six and a half years since Mark Ridge joined the organization. Ridge left a promising position at Pfizer to take on what he felt would be an extraordinary opportunity to lead the clinical operations team of a biotech leader that had just taken its Research & Development organization to a global level.

CSL Behring had multiple assets in development and Ridge and his team were tasked to deliver six new products to market over a seven year period. As Ridge understood more about the new position he was taking on, he quickly realized that there were significant challenges to address, including internal coordination, CRO performance, and the need to strengthen interactions with the sites conducting trials.

“We needed to clarify our internal processes, and our model of working with one single CRO was not working well,” says Ridge. “At the same time, we were upsetting long standing relationships with our investigators through insufficient interactions. I knew changes had to be made, and that the process would be a challenge. Patients depended on us to get the job done, so it was time to get to work."

**Become A Sponsor Of Choice**

Prior to Ridge coming onboard, CSL Behring had set up an exclusive relationship with one CRO to run its trials. In turn, CSL Behring relied on the processes of this partner. But 6 to 12 months into the partnership, issues began to surface. The partnership was supposed to result in easier, faster, and less expensive trials. Unfortunately, the partnership model was not achieving its goals.

“As a company, we had not fully considered how we wanted to manage clinical trials,” says Ridge. “We were focusing a lot on making that partnership work. I remember looking at myself, my team, and our model and knowing we had to transform how we conduct clinical trials.”

The changes made all supported one central theme: CSL Behring would become a sponsor of choice. It would be the sponsor company that patients, sites, and CROs wanted to partner with. “It was time to start investing in our operating model,” notes Ridge. “We needed to get our house in order and then ensure the CROs we worked with were clearly aligned with our philosophy and approach.”

**A Culture of Empowerment**

Ridge felt the key to making needed internal changes rested in proper leadership and management and in being an inspiration to others. He is passionate about his work and wanted other team members to feel the same way.

Therefore, he wanted his staff to feel ownership, believe they could solve any problem, and know they were backed by managers who would support them in achieving study goals. He felt the best way to do that was to create a culture of empowerment.

“To be successful in delivering clinical trials, you need to start by hiring the right people,” states Ridge. “That was one of the first things I did. I looked for people who were experienced but most importantly, had the same passion and drive for delivery that I had. Once you hire them, you need to be clear in setting the direction and then let great people do great things. I felt the best thing I could do was get out of the way and allow them to do their jobs. I have always felt that if you want outstanding results, you have to hire the right people, place them in an environment where they feel empowered, and make them accountable for the work they do. If you do that, you will find people can accomplish amazing things.”

**Find The Right Partners**

Next, the team focused on the partner model that was in place at CSL Behring. Having a single CRO partner that did everything was not a scalable model. No one CRO had experience in all the disease areas CSL Behring covered, and no one CRO would be able to perform all of the functions required of them. Therefore, early on, Ridge opted to replace the single CRO partnering model with an FSP (functional service provider) model that would employ key strategic providers with capabilities focused on certain functional areas.

“Essentially, I wanted to identify key areas where we needed help from partners and then find the company that would be best equipped to provide us with those capabilities,” he says. “We also needed to define the CSL process to then allow our partners to integrate with us. For example, we knew we needed help with data management. There is clear value in having the same company perform data management for every study. That is how you learn, become more efficient, and create higher quality databases.”

Using the same data vendor every time also eliminates the need for RFPs and vendor selection each time you’re ready to start a new study. Those inefficiencies were something Ridge hoped to eliminate. For the data management function, Ridge chose one vendor which now handles all of the data management for CSL Behring’s trials.

“With one data management partner, we have gone from focusing on simple processes to now focusing on innovation and technology capabilities that have helped our company scale to manage a larger portfolio of studies. Another company was selected as our exclusive partner to perform biostatistics. For therapeutic expertise we turn to whichever CRO has the most expertise in a given field.”

This new model obviously required multiple new vendors. Potential partners were put through a series of qualification tests and now the company has a portfolio of providers that best meet the needs of its operating model.

Although Ridge is now working with multiple CROs, he did not want to function under multiple operating models. Therefore, CSL Behring created an operating model that outlined how the company performs study delivery functions. Every section of the operating model gives an overview of how the company performs these functions, why it is done that way and the tools and technology that support the process.  Any employee in the company can access any section of the electronic document to learn not only how a function should be performed, but also why the company chooses to do it that way.

**Manage Your Vendors**

CROs are an integral part of the resourcing strategy at CSL Behring. Generally, more partners mean more oversight, but Ridge also wanted to stick to his goal of making clinical trials more efficient. Therefore, he sought to avoid performing oversight the same way companies have performed it in the past.

“An alarming trend I have seen in the industry is sponsor companies handing over control of a study to the CRO,” he says. “The industry is taking the accountability out of sponsors’ hands and making sponsors vendor managers, instead of study managers. This creates a toxic environment where sponsors are continually beating up their partners and blaming them for not being on track. The whole process also becomes an outsourcing exercise versus doing what is right for the sponsor.”

Ridge’s model is different. All studies are run at CSL Behring, and Ridge’s philosophy is very clear. “We run studies and we are accountable for the delivery of our studies.  We don’t blame CROs for failure. We want CROs to feel like they are part of our team. We hold each other accountable for delivery, set up our processes to achieve a successful outcome, and then work together to deliver. CROs are an important aspect of our delivery model, and we expect them to care as much as we do about getting our product to our patients.”

**Ensure Your Sites Are Reimbursed**

Being a sponsor of choice means keeping your partners happy, and that means making sure they are reimbursed in a timely manner. Site payments are a problem across the industry, and it's something Ridge knew he had to fix. "This is one of those areas where you really need to get inside the mind of your customer and understand the impact of not fulfilling one of your primary responsibilities and how that will impact their commitment to you," Ridge stated. Ridge felt the problem rested with CROs that were not paying sites in a timely manner, although he didn't understand why.

"We started putting pressure on the CROs," he says. "I needed to know what was going on. We were front-loading them with budget to pay sites, but for some reason it wasn't getting done. It turns out, this was a completely manual process with very little sophistication or focus. This is another problem I viewed as an ownership and accountability issue. There are certain capabilities that companies must control 100 percent, and I felt this was one of them. Sponsors need to have a system in place that works and can be properly managed to ensure sites are reimbursed for their work in a timely manner. You have to get this right."

To solve the problem Ridge and his team worked with an external company to install a system that integrated with CSL Behring's electronic data capture system. Data can now be accessed, in real time, from the data management system. Sites are now being reimbursed on time and each payment has a clear description and complete details. Ridge states complaints about reimbursements have now gone away.

Ridge was recently at a Linking Leaders meeting where a moderator asked if attendees felt site reimbursements were under control at their companies. Only 3 of 19 people raised their hands. While this is a problem that still needs to be fixed, he believes CSL Behring now has it under control.

"Site reimbursements are just one example of an area we needed to focus on to get CSL Behring better connected with investigators around the world," states Ridge. "We also needed to put more human elements back into clinical research. We needed to get more connected with our sites by focusing on our science, being more available to answer questions, and having a presence at our sites around the globe."

The clinical research team at CSL invested a lot of effort to become more connected with sites. It also implemented a new Clinical Oversight Manager role in 30 countries. That individual is the "face of CSL" to sites and ensures the company has strong relationships with sites and that sites understand the protocol and are appropriately running the study.

**Measures Of Success**

Thus far, the changes initiated by Ridge appear to be successful. The company has already received five product approvals and another approval is expected soon. The changes that Ridge and his team have implemented have stood up to inspections by the FDA, EMA and PMDA and the products are now helping people with serious and life threatening diseases.

To measure the Sponsor of Choice objective, Ridge knew he could only say his group succeeded in improving if he had the evidence to back up the claims.

For that reason, CSL engaged with Clinical SCORE to conduct a yearly survey of all site partners. Ridge wanted to hear from the sites who actually worked with his clinical team. The baseline survey was done in 2013 and since then, he has received annual feedback from 100 doctors and 100 study coordinators rating his team's performance. The surveys are often followed up with discussions to gain additional feedback.

"These surveys allow us to look in the mirror," says Ridge. "They have allowed us to determine that 80 percent of sites want to work with us again. We have statistically significant improvement over each of the last four years in every category, including budgets and contracts, how we manage studies, the quality of our protocols, and supporting sites from a patient recruitment standpoint. In clinical research, we know issues and challenges will arise. The main thing we have learned is that when you have strong relationships, it's amazing how quickly difficult problems can get solved."

Despite the recent success, Ridge notes the company is not resting on its laurels. "We are in a much better spot than we were five years ago," he adds. "We want to see continuing improvement. We will always look for new areas in which to focus. We need to make sure we do not get complacent. The work we do in bringing products to our patients is too important. We have to continually push ourselves to be the best we can be."