

Merge Healthcare Delivers Time-Savings for Large Pharmaceutical Company's High-Stakes Clinical Trial

The Client

A major, global pharmaceutical company needed to conduct a clinical trial that tested an important pediatric respiratory treatment versus a placebo.

The Challenge

The trial involved 1,200 English and Spanish speaking pediatric patients at 170 sites in the United States and Canada. Because of the nature of the study, patients and their caregivers had to be screened and enrolled in the back-to-school timeframe — no less than 4 weeks before school started. If patients missed the screening window, they were ineligible to participate in the trial.

A shift in the protocol approval date to June made the already strict trial timeframes even more challenging. While enrollment sites in the North started school in September, trial sites in the South started school in August. This meant the trial systems had to be ready for enrollment by July, giving only 4-8 weeks of setup time followed by just 4 weeks of screening time to meet the back-to-school timeframe requirement. Even the Spanish-version screens in the electronic diary system that would be used in the trial had to be translated and tested by users within the 4-8 weeks of setup time.

As if things weren't challenging enough, the pharmaceutical company wanted to do a sub-study for an exploratory endpoint. The sub-study required the collection of additional specimens from 200 of the main trial's patients. Those specimens would be analyzed by a specialty lab. Whatever system was used to handle the study had to be able to manage that additional lab data without interfering with the larger trial.

The pharmaceutical company hired an experienced Clinical Research Organization (CRO) to handle the trial. The sponsor assessed the situation and concluded that due to the complexity of the study and the strict timeframes involved, it was unlikely the trial would be successful.

Facing such a grim possibility, many studies might be postponed. Delaying this trial, however, would have required postponement for a whole year to get to the next back-to-school timeframe. Keeping the entire project on hold for a year presented a very costly and undesirable scenario for the pharmaceutical company, especially given the significant contribution the treatment was expected to make to the pharmaceutical company's overall financial performance in the coming years.

Pressure mounted for the Sponsor and CRO to find a way to ensure this complex trial would be successful. Given the need to conduct this trial in a timely and efficient manner, the Sponsor looked to its partners for viable solutions. The CRO urged the pharmaceutical company not to use its in-house clinical trials system. The in-house system offered only some of the functionality needed for the trial, and therefore would require that the CRO spend valuable time coordinating a number of solution providers and their disparate systems. Given the trial's complexity and tight enrollment schedule, the CRO stressed the risk this complex patchwork of in-house and third-party solutions presented to the success of the trial.

The Solution

As an alternative approach, the CRO recommended that the pharmaceutical company use Merge Healthcare for the study. The Merge Healthcare fully-integrated eClinical Suite provided everything they needed — electronic data capture (EDC), interactive voice response (IVR), electronic patient diaries (ePRO) and a clinical trial management system (CTMS) — from a single source. This approach would save time getting the trial up and running, and simplify how efficiently the clinical data could be collected, managed and analyzed. They expected that by using the fully-integrated Merge Healthcare system, they could simplify the study process for all involved, saving precious time and allowing this trial a real chance at success.

With its client's approval, the CRO worked with Merge Healthcare to implement the Merge IVR, EDC, and ePRO systems. The CRO also implemented the Merge CTMS to hold all site information and manage the 200 trial sites. In no time it became clear that using the Merge Healthcare eClinical Suite was key to the trial's ultimate success.

One Solution, One Source

The CRO responsible for day to day management of the trial found that dealing with just one vendor to manage EDC, IVR, eDiaries and the CTMS simplified setup, support and ongoing trial management. The CRO and Sponsor were given a primary, dedicated Merge Healthcare Project Manager for all of the technologies used, giving them a single point of contact to address any system issues and get them resolved quickly. In addition to having fewer people to manage, Merge Healthcare provided the CRO with a dedicated 24x7 helpdesk staffed by Merge Healthcare employees trained both on the trial protocol and on the systems. This same helpdesk staff trained the site coordinators and provided them with training manuals. They also provided quick reference cards for the sites as well as the enrolled patients and their caregivers. This continuity of systems, support and training accelerated the trial set-up process — so much so that they were able to get the trial up and running in time for the back-to-school enrollment.

Enrollment: On Time & On Target

Once sites were trained and enrollment was underway, the CRO used the Merge IVR system to track screening, enrollment, drug supply, and discontinuance. In addition to ensuring all 200 sites had the drugs they needed for the trial's 1,200 patients, the IVR helped the CRO ensure the trial achieved the right number and type of enrollees for the trial, and that they achieved a relatively even ratio of enrollees between the sites in the North and South, even though enrollment in the two regions started a month apart.



The Merge Healthcare system enabled the CRO to see in real time when a patient was screened and randomized, which was critical to keeping the right level of enrollment and the right geographical ratio of enrollees. If Southern site enrollment was strong, the system helped them decide when they should cut off enrollment to avoid enrolling too many patients from Southern sites, which would waste money. But the system also allowed them to track some over-enrollment in the Southern sites in case Northern enrollment came up short. If, however, the Southern sites missed their enrollment goals, the CRO could view that in the IVR system and increase the Northern enrollment goals quickly to make up the shortage. Having this information in real time was critical since this adjustment would require the Northern sites to scramble to meet those higher enrollment goals. Fortunately, the Merge Healthcare system helped the CRO recruit on target patient populations and deliver a far lower screen fail rate than was anticipated. This resulted in more patients being randomized than were actually needed, despite the tight timeframes for the study. That avoided the costs that would have resulted if additional sites were needed to screen more patients so they could get randomized and meet enrollment goals.

In addition, with a limited trial budget, this study did not leave much room for failure and discontinuance. The CRO used Merge EDC to see inclusion and exclusion criteria in real time, which allowed the CRO to make sure sites were getting the right patient populations and excluding inappropriate patients as soon as possible rather than spending money on them unnecessarily.

Common Interface Across Systems

Another benefit of the integrated Merge Healthcare system that contributed to the trial's success was the common interface it offered the study sponsor, coordinator, sites and physicians. Unlike patchwork solutions that require users to learn separate IVR, EDC and ePRO systems and convert data from one system to another, the Merge Healthcare system offered a common interface that made it faster and easier to train people for the trial and made it easier for the sponsor, CRO and study coordinator to collect, monitor and manage data. This ease of use was most evident in the average page turns achieved when sites and study coordinators entered patient data into the Merge EDC system.

Merge Healthcare users can view trial data through one secure Web-based interface instead of having to go back and forth between several systems. For example, a user in the EDC system can view information uploaded from that patient's ePRO data and view labs that were imported and appended to that record. The Merge EDC system can import any external image or lab data like labs, x-rays, EKGs, and such into the system. With this capability, Merge Healthcare allowed the CRO to make the most of the enrollees through a sub-trial without difficulty. Data from the specialty lab that analyzed the specimens from the 200 sub-trial patients was imported and appended to the patients' records.

Keeping Sites Happy

The common interface and integrated data access also improved the likelihood that the 170 study sites would be willing and able to aggressively meet their enrollment goals. They were already faced with the daunting challenge of finding pediatric patients and their caregivers who were willing to participate in a clinical trial during summer vacation. Add to that challenge the fact that those patients and caregivers spoke English or Spanish, and it became even more critical that the CRO make the trial's EDC and ePRO systems as easy as possible for the sites to use.



Patients and their caregivers were issued and trained on how to use their ePRO during their first visit. Before handing over the PDA, the site coordinator would set the ePRO to display screens in the language of that patient. Thanks to Merge's sophisticated ePRO software, the PDA could be set for either Spanish or English. Site coordinators didn't have to worry about how many PDA's of which language they would need. This is just one example of how the Merge Healthcare system simplified things for the trial sites.

In addition, the Merge ePRO system supports features like larger font sizes and similar advanced functionality that made it easy for patients and their caregivers to provide more accurate data. Patients answered questions at intervals as prompted by the ePRO which captured the data. For questions that had to be answered within a certain timeframe, the ePRO provided a time window during which the question could be answered. The ePRO would not allow a patient to answer the question outside of that time window, eliminating faulty patient recall encountered by trials that use paper-based diaries. Answers showed up in the Merge Healthcare system for review each night after being transmitted over a phone line. Patients were instructed by the sites about how to transmit data nightly via a simple phone splitter that attached to their ePRO. The ePRO automatically downloaded the data at 3am without interrupting phone service before or after transmission. Once transmitted, the data was immediately available for review.

Safety First

This real-time turn-around was central to the study's success as well as patient safety. Safety features embedded in the Merge EDC system could alert the study coordinator and the sites immediately if a critical parameter was met that might trigger a serious adverse event (SAE). For example, the system would know that if blood pressure gets to a pre-designated level, a patient could have a SAE and should be discontinued from the trial. The system would alert the study coordinator immediately by cell phone, pager, or fax machine to notify the patient of the possible SAE. With a paper-based study, there is typically a delay of several days before a patient's ePRO data is available for review, and even then the study coordinator might easily overlook a criterion that could make it unsafe for a patient to continue in the trial. Merge Healthcare systems overcome those limitations and deliver advanced features that help to ensure patient safety.

Due to the complexity of this trial and the strict timeframes it presented, the successful completion of this trial was a significant achievement for the large pharmaceutical company, demonstrating to them just how many efficiencies and benefits the fully-integrated Merge Healthcare eClinical Suite delivered to all parties involved in the study.

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