

Merge EDC Saves Biotechnology Firm Time and Money

+ *Merge's Electronic Data Capture solution provides functionality and flexibility sponsor needs to save time, money and ultimately lives*

The Sponsor, a Massachusetts-based biotechnology company committed to helping people with serious diseases, chose Merge Healthcare in 2001 to design and manage the first of eight groundbreaking studies addressing a treatment for a rare but deadly glycogen storage disorder. Merge's Electronic Data Capture (EDC) solution played an important role in helping the Sponsor earn FDA-approval for a pediatric treatment for the disease, and is at the heart of the sponsor's ongoing efforts to understand and find a treatment for the disease in older children and adults.

The first study with Merge Healthcare involved 30 pediatric patients who ranged in age from birth to 26 weeks. The global study required patients to receive a drug infusion at a hospital each week for 112 weeks. These patients also required approximately 36 lab tests per week.

With so many visits and labs required, and a high propensity for serious adverse events in these very fragile patients, the sheer volume of pages required for this study would have made it tremendously difficult to do on paper — but that wasn't the only reason the sponsor decided to use Merge's EDC solution. The Sponsor needed a data capture system that could provide maximum flexibility to accommodate frequent protocol adjustments as well as innovative new ways to manage large volumes of data.

Because the study coordinators were able to manage all of the amendments electronically, the EDC system knew when patients should have a certain form, so even with frequent amendments, only the right pages showed up for a patient, avoiding unnecessary work and ensuring the right data was captured for each patient.

When the first study reached 112 visits it appeared the drug was working because many of the patients who were not expected to live were still alive. The Sponsor decided to set up a new study for patients aged 26 weeks and older, and once again, Merge's EDC system displayed its versatility. Merge created an innovative mechanism that allowed the Sponsor to easily transfer patient data from one study EDC database to the other so they could be more easily managed. The flexibility that EDC provided to do this transfer meant sites didn't have to do any of the subject start-up tasks normally required for patients. In addition, along with the visit data, Merge transferred important patient information such as data about Serious Adverse Events (SAEs), so that sites didn't have to reference the old database to view this information. This put everything that was needed about a transferred patient in one central repository.

The study sites also benefited from a variety of other timesaving solutions provided by Merge EDC. For example, due to the fragile condition of the patients in the two pediatric studies, patients had many SAEs. Typically, each SAE requires a detailed form to be filled out which is

then appended to the patient record. To save time for site coordinators, Merge added the SAE form to the study's online reporting center. There, it could access the study database where all of a patient's data is captured. With just the push of a button an SAE form pre-populated as many of the fields as possible with information from the database. Site coordinators then had to fill in only the missing details to complete the SAE form. To make the SAE reporting process even more efficient, the Merge EDC system routed these SAE forms, just as it can route other important reports, to the sponsor and other parties involved in reviews.

Another way EDC made it easier to manage its studies was through an innovative viewing application that Merge added to its online reporting center. With so many visits, labs and SAE's for each patient in the studies, coordinators found it difficult to scroll through all the data that would display when they looked up a patient record in the online reporting center. To solve this problem, Merge created a Hide Visit application that allowed viewers to hide rows of data so they could view only the entries of a patient record most relevant to them. This unique application allowed the Sponsor to manage the workflow better without getting lost in the large quantity of data collected during the studies. Merge's EDC technology further simplified work for the sites by providing electronic edit checks that were programmed to know which data ranges a patient's results should be compared to. As children in the first pediatric study grew over the study's 2-year period, the ranges considered "normal" for their age would change constantly. With Merge's EDC technology, the edit check system knew to look at the age range of the child and make electronic checks using only the data ranges appropriate for that child at that time. With over 1100 edit checks in the first study alone, the ability of EDC to know what range it should use for each patient helped clean the data without getting false edits, saving time and improving data quality.

Merge also created a PDF generation tool that aids in the electronic submission of data to the FDA. This delivery mechanism was initially used to submit data for the Sponsor's second pediatric trial after the company found that when submitting data for the first study it was difficult to make critical data stand out among the overwhelming amount of data collected. Rather than simply giving the Sponsor the entire database and Printable Data Files (PDFs) of the case books as it did for the first trial, Merge also customized its PDF generating tool so the Sponsor could make critical data more obvious than it would be through just a review of the case books. One feature of this tool allowed the Sponsor to add hyperlinks to the pages with notes, so viewers could click to read the actual correspondence about that note between the monitor and the site. This eliminated the need for people reviewing the PDF's to flip back and forth from pages to appendices, making it faster and easier for the FDA to review and understand the submitted data.

Merge also simplified the Sponsor's FDA data submissions by importing right into the EDC database all of the lab data collected by the central laboratory that was used for the studies. The lab put the data on Merge's secure FTP site and Merge imported the data right into the Sponsor's case book and database. With about 36 lab sessions per patient weekly, the ability to import lab data avoided a lot of data entry and the typical errors associated with it. Importing the data also allowed staff to see how labs were returning while the study was going on rather than waiting until the end of the study to view that information. Monitors could look online to see how patients were progressing before flying to a site, further saving time and money by reducing travel. In addition, those same lab results were included in the database and PDFs of the case books generated for FDA submission. As a result, the Sponsor required only one transmission to the FDA and avoided the complex task of merging of data between the lab system and their data center.



Encouraged by the success of its first pediatric trial, which resulted in approval in Europe and the United States, the Sponsor is pursuing approval for that treatment in older children with the disease. The Sponsor has also conducted similar trials to understand how the disease behaves in adults and how it might be diagnosed in adults. These studies offered an opportunity to bring some of the study development in-house using Merge's Technology Transfer program. Through this program, the Sponsor licensed Merge Design technology to create the studies themselves. The Sponsor's team of developers received extensive training by Merge and collaborated with Merge during the development process, often by using the secure Merge FTP website. Merge then deployed the studies for the Sponsor.

This collaboration worked so well that the Sponsor is now using Merge's Technology Transfer program to create inhouse a new protocol for an adult treatment study for the disease. The Sponsor will use what it can from a library of databases already created by Merge to save study start up and development time. Once the study is created, the Sponsor will have Merge put the study through quality control, and then deploy it. As the Sponsor and Merge continue to work together to find a treatment for the disease in older children and adults, the Sponsor continues to employ Merge EDC technology to its full potential, saving time, saving money, and ultimately saving lives.

About Merge Healthcare

Merge Healthcare is the leading provider of enterprise imaging and interoperability solutions. Merge solutions facilitate the sharing of images to create a more effective and efficient electronic healthcare experience for patients and physicians. Merge provides enterprise imaging solutions for radiology, cardiology and orthopaedics; a suite of products for clinical trials; software for financial and pre-surgical management, and applications that fuel the largest modality vendors in the world. Merge's products have been used by healthcare providers, vendors and researchers worldwide to improve patient care for more than 20 years. Additional information can be found at www.merge.com.

Merge Healthcare
4000 Aerial Center Parkway
Morrisville, NC 27560-8508
919.653.3400
www.merge.com

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