

Integration of a Medical Device in a Clinical Trial

The Client

The sponsor is a prominent university that boasts almost 30 years expertise in research and clinical care. It is a nationally recognized center for health care, biomedical research, and medical education while consistently ranking among the nation's leading hospitals in a variety of specialty areas. Its faculty of physicians and scientists continues to serve the community by spearheading research, caring for a large patient population, and providing many unique regional services, such as a burn center, an eye center and a cancer center. From cancer to heart failure to headaches, clinical trials are a way of life for the sponsor and the physicians and researchers that regularly engage in research involving thousands of participants.

This clinical study is being conducted at nine sites. This study is designed to test whether brain volume levels in head trauma patients can be detected earlier using the diagnostic device versus conventional bedside nurse measurements. There are two arms of this study: the inpatient segment comprising 200 enrolled patients and the outpatient segment that comprises 64 patients. The study is being conducted using a handheld diagnostic tool that provides quantitative measurements of the reaction time of a pupil to light.

The Business Challenge

This study is unique in that there were two different stakeholders with vested interest in this study. The company that manufactured and marketed the device and the university that conducted the clinical study each had different roles, expectations and needs that had to be addressed. The device company's interest was focused on having doctors, nurses and hospital staff use the product so that down the road they would recommend the purchase of the product. The university's interest was geared more to the actual implementation of the device.

The study development process did not follow a typical study start up procedure. In this case, the device manufacturer requested that the Merge Healthcare system be put through a validation process to ensure that it met with the GMP standard. So not only was the system subject to Merge Healthcare's own review process but that of the sponsor. This impacted the length of time to study start up but was successfully managed by the Merge Healthcare team.

In order to meet the needs of the university conducting the trials, there were many challenges to address in order to ensure the proper implementation of this clinical study. Organizing the vast amount of data collected was of major importance. Each of the 200 inpatients was tested every 30 minutes for the duration of 72 hours or 144 times within the measurement period. Therefore for the 200 inpatients in the study, there was a total of

the end result was that the most precise data was collected and available for review in a centrally located format

28,800 data points to be gathered. And each of the outpatients was tested every 30 minutes for 24 hours or 48 times in the measurement period for a total of 3072 data points to be collected. Given the large amounts of data to review and process, a system was needed to manage all the data and eliminate as much error as possible. The primary goal was to create a system in which this data could be seen and reviewed in a user friendly and time sensitive format. Ideally the sponsor wanted to view the data in an eCRF.

The Merge Healthcare Solution

Diagnosis

The project began with an initial consultation between key stakeholders involved in with the delivery of the clinical study. From this the parties involved were able to identify the key challenges:

The files themselves created a number of challenges:

1. The device creates multiple files each containing data from one or more patients.
2. Files can have duplicate data across files.
3. Some of the data is bad. This includes invalid patients, invalid dates, and out of range measurements.
4. Files are not centrally located. They are distributed on individual computers at 9 different sites.
5. Data is not formatted into records for loading into a database. Data appears in blocks of text going down the page. Each block has a variable number of fields.
6. Data may not be received in order.
7. A variable number of measurements per patient.
8. The system must automatically process and load any available files nightly.

Solution Development

The sponsor had very specific requirements in terms of how the data was to be reported and displayed in the CRF. The data measurements needed to start within a three-hour window of the reported date in the CRF. It was necessary to organize the data chronologically based what time the test was administered. Because the individual study time lasted three days, the data must be segmented into three separate 24-hour increments based on the initial start date and time. The staff also needed the ability to add missing information that came in later in the sequential order even if it was between existing records. The data needed to be assigned to a specific patient and should not allow invalid data ranges.

In addition, the sponsor also requested error reporting so that they could fix incorrect records in the files. Also important was the ability to identify the cause of the error, especially important because a medical device could be the cause or it could be operator error. The ability to correct errors in the system was particularly important given the fact that there was no way to edit the source data because once it was captured and stored in the handheld device there was no way to access the information. trials was able to design a system that would manage all these requirements set forth by the sponsor. The system was also able to comply with the validation guidelines required by the device manufacturer.



Implementation

The technology used in the integration of the medical device data and the EDC is a truly automated process. The eye measurement data that is generated from the medical device is downloaded and the files are placed in a transfer directory on the user's desktop. Once the files are placed in the transfer directory, etrials Quick Study Transfer program retrieves these files and begins the integration process. The imported files are in an unusable format so a file processing application was designed to create individual records from the "blocks" of data. Next the application retrieves the patient list stored in Quick Study Capture in order to match the patients to the newly created individual records. At this point, the system is also checking for errors in order to prevent invalid data or duplicate data from populating the eCRF. An error report is generated detailing the invalid data as well as the cause of the error so that the files can be edited directly. The next step is to sequence the data by patient and time including processing data that has arrived out of sequence. It is at this point that the data is loaded into the eCRF and the integrated data is available for review.

Metrics

- eCRF development from start of process to first review: 8 days
- Edit check development from start of process to first review: 2 weeks
- 300 pieces of data per patient x 200 patients: 60,000
- Over 30,000 device measurements integrated and represented in the eCRF

The Business Outcome

With the integration of the medical device data and EDC, the end result was that the most precise data was collected and available for review in a centrally located format. The sponsor was able to confidently know that the data that was being tracked and reviewed as well as the conclusions being drawn based on this information would be accurate. Additionally, the study provided further validation of the medical device and its use for this new procedure.

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

MERGE[®]
Healthcare