

Integrating EDC and IVR: Merge Healthcare & The Medicines Company

The Client

The Medicines Company meets the demands of the world's most advanced medical practitioners by developing products that improve specialized care. The Medicine Company creates value using its range of clinical and commercial skills to develop products acquired from leading life sciences innovators. The company is publicly traded on the NASDAQ under MDCO. The company was founded in 1996 and is headquartered in Parsippany, New Jersey.

The Medicines Company was founded on the premise that there are products developed that could yield strong sales but may not be a strategic fit for large pharmaceutical companies to produce. Their corporate strategy is to acquire drugs that are in the late stages of product development but are undervalued by the pharmaceutical or biotechnology companies that developed them. Once a drug is acquired, the Medicines Company completes the clinical development and regulatory processes and then commercializes the drugs in the U.S. and abroad.

Once such drug is Clevelox (clevidipine), a short-acting calcium channel blocker that can be used to reduce blood pressure, obtained from AstraZeneca PLC in 2002. In initial clinical studies, the drug Clevelox has demonstrated the potential to precisely control blood pressure, which is often required during, and following surgical procedures. Currently, a series of clinical trials are being conducted to determine the efficacy and safety of the drug. If approved the drug could become a part of The Medicines Company's growing acute cardiovascular care franchise.

The Business Challenge

With five Phase III clinical trials spanning 80 sites and 1700 enrolled patients, there were many challenges facing The Medicines Company. Faced with an aggressive schedule for completing the study, multiple study sites, and a large number of patients, the sponsor needed a system that could address these obstacles. Given the schedule and limited resources, the sponsor needed a way to view all the data in a useable format that was centrally located. Ideally, they wanted the IVRS data to pre-populate the eCRF. With the large number of sites and patients enrolled in the five separate trials, the minimal staff of program managers needed a reporting system that allowed them to review all the data from one location.

The Merge Healthcare Solution

Diagnosis

The project began with a strategic consultation between key stakeholders from all parties involved with the delivery of the clinical study. From this phase, Merge Healthcare and the



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Sponsor were able to identify the key challenges as well as the opportunities for improvement:

1. There are five Phase III clinical trials for Clevelox currently in progress: two efficacy and three safety studies
2. In the two efficacy studies, there are 20 sites with 200 patients total. One efficacy study will test the pre-operative effects of the drug in cardiac surgeries and the other will test post-operative effects
3. In the three safety studies there are 60 sites with a total of 1500 patients
4. All sites needed training, as well as Sponsor and Merge Healthcare personnel
5. Anticipating and proactively addressing import/export issues for the movement of IVRS data into the EDC database structure
6. Developing new customized reports from the integrated data sets
7. Providing valuable metric reports to the Sponsor allowing for better trial management and decision making
8. Working with other suppliers on specific data management requirements

Solution Development

The Medicines Company challenged Merge Healthcare to find the best method for the accurate integration and reporting of IVRS and EDC data. The integrated offering would be used in the series of five clinical trials designed to test the efficacy and safety of Clevelox.

Additionally, to save time and speed up the data entry process, The Medicines Company wanted the IVRS data to pre-populate the eCRF within the EDC software.

The sponsor's decision to use Merge Healthcare and Merge EDC™ was based on our ability to provide viable solutions quickly and with accuracy. The challenge was to find a way to integrate the data gathered via IVRS with the EDC data in one usable format. The IVRS system was being used to enroll patients and the sites as well as to collect pertinent study information.

Merge Healthcare was able to integrate the trial information gathered from all the sites via Interactive Voice Response System (IVRS) and pre-populate the eCRF. The IVRS system captured such information as drug supply management data, randomization, as well as demographic information (patient age, gender and initials), date of randomization and patient number assigned. Once this information was collected, the sponsors could view the compiled data from all sites and patients in real time as it was occurring.

Implementation

The actual technology used in the integration of IVRS and EDC is a streamlined process. The IVRS data is placed on the FTP site at pre-determined times throughout the day. The information is then pulled from the FTP site within a half an hour of the posting. The IVRS



data retrieved is processed through a server application that was developed by Delphi. This server imports the information and maps the data based on a XML file configured specifically for the study. The data is then converted into the format that will be used in the study database. The converted information is inserted into the database and is then available for review via Quick Study Capture. At this stage an email is generated and sent out detailing the new information that has been entered into the system.

Metrics

- eCRF development from start of process to first review: 8 days
- Edit check development from start of process to first review: 3 weeks
- Time to program IVRS integration: 1 week
- From final protocol to deployment: 8 weeks
- Seven customized reports showing integration of IVRS and EDC data
- Pre-population of IVRS data in eCRF (see screen below)

The Business Outcome

With the IVRS and EDC data located centrally, program managers were able to monitor the sites to ensure that they were entering the information within two days of randomization. Also with the information available in real time, the sponsor has the ability to make informed decisions on the viability of the drug as the study progresses. By integrating this data, The Medicines Company was able to see site compliance, how proactive their sites and monitors were being, and was able to verify site status in order to initiate site payments on a timely basis. The overall benefit of data integration is that it will enable the sponsor to meet the aggressive frozen file timeline.

"The benefit of data integration is that it offers more control over the study," says Judy Sromovsky, Study Director from The Medicines Company. "It automates what used to be separate manual processes and allows the data to be stored and reviewed from one location in real time."

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.

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