

Merge IVR/IWR™: Providing Dynamic Dual Randomization in Clinical Trials

The Client

As a global leader in medical research, the foundation involved in this study conducts numerous trials each year. For this study, the sponsor partnered with both a pharmaceutical company and a medical device company to research two common cardiovascular drugs and their interactions with a medical device.

The Business Challenge

This phase IIIb trial had both complex and time sensitive factors critical to its deployment. Because the protocol required over 40 strata, involving two drugs and two variations of a stent, it required complex programming including dynamic dual randomization. Adding to the complexity of this six year study was the need to recruit a large global patient population. The patient enrollment target for this trial was 3400 screened and randomized subjects.

Given that patient recruitment is a primary issue facing sponsors, choosing sites that are experienced and capable of recruiting patients quickly and efficiently was paramount. Due to the limited number of potential, qualified sites, sponsors are often forced to compete to obtain commitments from investigators. With 200 sites across fifteen countries needed to conduct the study, as well as the competition for sites, there was extreme urgency to get started. With some of the countries involved having few qualified sites, the need to secure them quickly was further elevated. It was essential for the sponsor to get the study up and running quickly in order to secure the most experienced sites.

The Merge Healthcare Solution

To address their challenge, the sponsor turned to Merge Healthcare not only to provide dynamic dual randomization but to also meet their tight timelines. The protocol required a method that would first randomize by drug and then secondly randomize by device. Given the intricacy of the randomization, coupled with multiple language translations, the sponsor needed a vendor-partner and IVR solution to address the situation quickly and accurately.

Merge Healthcare was able to provide integrated study analytics by incorporating Merge IVR and Merge EDC. By creating a customized supply control workflow, Merge Healthcare made it possible for the sponsor to easily manage drug supply at the site level based on actual patient enrollment. Merge Healthcare also created automatic study-wide caps to better manage enrollment at the different sites, aiding the sponsor in ensuring that the correct quantities of resources were at each site, thus reducing wait times for extra shipments, wasted materials, and costs.

Metrics

- IVR development from start of process to first review: 1 day
- From final protocol to deployment: 5 weeks

the advanced algorithms powering the IVR solutions's dynamic randomization resulted in more efficient resource allocation

- Language translations: English, Polish, French, Italian, and Spanish
- Site locations: US, Canada, Denmark, Italy, France, Netherlands, Sweden, Israel, Argentina, Brazil, UK, Spain, Poland, Germany, and Australia

The Business Outcome

From start-up and deployment to the present, Merge Healthcare has been able to handle all of the challenges and provide the best solutions and efficiencies.

With Merge Healthcare successfully deploying the study within five weeks from final protocol, the sponsor was able to secure commitments from the sites, ahead of the competition.

The advanced algorithms powering the Merge IVR solution's dynamic randomization resulted in more efficient resource allocation. This eliminated the need for a biostatistician to create and manage enrollment algorithms, thus allowing them to focus on analyzing the data.

After deployment, the Merge IVR solution was able to capture information such as patient enrollment, drug supply, demographics, and two randomization dates, along with other study data. After this information was collected, the sponsor was able to view the compiled data from all sites and patients through the administrator web interface in real-time, significantly improving study performance and decision making.

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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