WHY SYNTERACTHCR?

A full-service CRO, SynteractHCR has a proven track record of success in all phases of clinical development.

Shared Work – Shared Vision: This is a promised standard, the way we do business. It conveys our collaborative, customized approach to conducting trials tailored to your needs, which meet or exceed your expectations.

Case Study: Asthma Trial

Introduction

SynteractHCR, Inc. was sought out by sponsor MediciNova, a publicly traded biopharmaceutical company headquartered in San Diego, for assistance on a Phase 2 asthma trial, MN-221-CI-007: A Phase 2, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of MN-221 in adults with acute exacerbations of asthma. MediciNova initially chose a global CRO for this study, not realizing that SynteractHCR had international capabilities. However, according to Dr. Kazuko Matsuda, chief medical officer, and Dr. Kirk Johnson, chief scientific officer, the previous CRO did not proactively handle the study and a change was needed:

"As the MN-221-CL-007 trial was ongoing, we decided that certain issues with the CRO warranted reconsideration of our initial choice. Based on our positive experiences with SynteractHCR on previous trials, we decided to solicit their work on this trial. This turned out to be a wise decision as SynteractHCR worked closely with us to assume the CRO's responsibilities with diligence, reliability and professionalism from each of their respective departments. The trial ended in Spring, 2012 and we were highly satisfied with the quality of work, especially with respect to the biostatistics department's efforts in the data analysis, and positive working relationship with the SynteractHCR team."

Challenges

SynteractHCR had to pick up the study mid-way through the trial and yet operate under the original timeline. Due to lack of communication from the prior CRO, sites had become frustrated with the study. Initially, the previous CRO was not willing to provide SynteractHCR study data collected on patients to date (safety data or clinical data), and SynteractHCR needed the data immediately in order to meet the project deadline. The prior CRO had only entered 31 of the targeted 200 patients in the database. At the same time SynteractHCR was developing solutions to address issues surrounding study data, SynteractHCR also had to assist with two of the international site closures. Additionally, inclement winter weather during 2010 presented subsequent challenges such as power outages, cancelled flights, facility shut downs, and delivery failures.

Our Solutions

The project was initiated in July, 2010 and the SynteractHCR team responded rapidly to the challenges at hand. In September, 2010 the SynteractHCR team was identified, and hit the ground running. They provided regular, detailed project updates to MediciNova. When the project was initially rescued, SynteractHCR identified that in order to move the study forward, study data would have to be re-entered. SynteractHCR advised the sponsor and developed a plan to gather, enter and manage the data to ensure the study met timelines, quality standards and ultimately, was FDA audit ready. SynteractHCR completed a highly customized database build by October, 2010. All data were entered by Christmas, 2010, and 50% of total enrollment was met by March, 2011. Throughout the trial, SynteractHCR had proactive communication with sites and worked hard to reengage the sites' interest in the study and build trust as the new CRO. SynteractHCR deployed a strong team of CRAs dedicated to maintaining visibility with nurses and ER doctors critical to recruiting

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patients. Upper management at SynteractHCR supported the project and provided the necessary resources to support its success.

Successful Results

SynteractHCR surpassed the prior CRO's results in five months: the prior CRO had the project for 17 months and enrolled 31 patients, while SynteractHCR enrolled 145 patients in 22 months, achieving the study's enrollment target. Under SynteractHCR's strong project leadership there was greater attention to detail that ensured overall study and data quality. Under SynteractHCR's management, queries averaged 43 per patient (7500 total for 176 patients) as compared to the prior CRO where queries averaged 129 per patient (4000 total for only 31 patients).

Multiple sites stated that MediciNova made a 'good move' switching to SynteractHCR. Since study completion, MediciNova and SynteractHCR have maintained a strong, ongoing working relationship.

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