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: Migraine Pain

Introduction

NeurAxon is a small pharmaceutical company headquartered in North America focused on discovering and developing novel pain management solutions for various indications.

SynteractHCR partnered with NeurAxon at the beginning of their clinical research programs for the development of their first compound in 2007. Since that time, SynteractHCR has been NeurAxon's primary provider of CRO services working on more than 10 studies with two different compounds in multiple pain indications.

In 2009, SynteractHCR partnered with NeurAxon to execute two Phase II studies for their lead compound. The studies were designed to evaluate the safety and efficacy of the product in migraines with and without aura. The study included a single dose of the study treatment and compared results versus an active comparator and a placebo arm. The trials were conducted at clinical sites in the US and Canada. SynteractHCR provided the following services for the trial: site identification, site selection, monitoring, IVRS, data management, safety case processing and reporting, biostatistics, clinical study report, and project management.

Challenges

The study presented logistical issues due to NeurAxon's study team personnel being located across North America. Enrollment timelines were critically important to the company and its investors. In addition, SynteractHCR was handling two studies for NeurAxon simultaneously due to the related indications, and similar design. Patient enrollment occurred quickly so resources needed to be carefully managed to maintain study progress and ensure the data collected was of the highest quality. An additional challenge was related to the study drug itself which was provided to the subjects to self-administer at home.

Our Solutions

SynteractHCR developed a sound strategy to meet the challenges presented by the study.

The project team SynteractHCR assigned to the study included both East Coast and West Coast project management and cross-functional staff members to allow for coverage that aligned with the location of the client's study representatives.

To capture efficiencies across the similarly designed studies that SynteractHCR managed for NeurAxon, a comparable project team structure was adopted, while at the same time factoring in the need for the teams to function independently.

In order to manage monitoring at the pace needed to achieve study objectives, regional based monitoring teams were geographically arranged in order to reduce travel and allow for flexible visits. Additional "floating" monitors on the team could supplement monitoring efforts at sites with heavy workloads or competing demands.

Since enrollment timing was identified as the most critical factor impacting study success, SynteractHCR identified primary site lists with a 30% overage to provide the option to

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proactively replace underperforming sites while maintaining study momentum.

To manage patients administering medications from home, SynteractHCR developed an automated IVRS system and reporting that tracked randomization and dosing of subjects. The system alerted the sites after a patient had dosed and needed follow-up. This allowed the study team to track dosing in real time and manage the expected workload at the sites.

Successful Results

Both of the Phase II migraine studies completed enrollment earlier than scheduled. The IVRS system allowed SynteractHCR to carefully track the exact number of doses and provided the ability to manage the study according to the protocol design.

Study 1 – Enrollment projection of 6.5 months; actual enrollment of six months.

Study 2 – Projected enrollment timeline of seven months; actual enrollment of four months.

Following the completion of these Phase II studies, SynteractHCR and NeurAxon continued their partnership with the development of NeurAxon's second drug candidate. The new program has been underway for two years with three initial studies completed. SynteractHCR and the client are currently planning the design for two Phase II studies that will begin this year in two separate pain indications.

Tom Lategan, Vice President of Regulatory Affairs at NeurAxon, stated, "As a small company we have relied heavily on SynteractHCR's experience and infrastructure to give us the reach to conduct multicenter, multi-country studies. SynteractHCR has worked well with our other vendors and consultants, and has been a pleasure to work with."

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