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: Phase II Trial in Ulcerative Colitis Patients

Introduction

Sigma-tau is an important Italian pharmaceutical group with a major international presence, active for more than half a century. Today, Sigma-tau is a leader in advanced research. Its goal has been to actively improve patients' quality of life while maintaining consistent relationships with scientific institutions internationally involved in the development of joint projects and the implementation of original and innovative research programs.

This study on ulcerative colitis was designed to evaluate the clinical, endoscopic and histological efficacy of two combined dosages of Propionyl L-Carnitine in comparison to placebo in patients affected by ulcerative colitis under oral stable treatment. The study was a phase II, parallel-group, randomized, multicenter, double blind, placebo controlled study. Initially, a total of 120 male and female patients were planned to be randomized in 14 experimental sites in Italy.

Challenges

The study's original deadline was September 2006, but after 12 months, only 13 patients had been randomized at the Italian sites. SynteractHCR stepped in to begin a rescue study and committed for study set-up and initiation in Russia (five sites), Poland (three sites) and Lithuania (two sites). This entailed handling regulatory and ethics committee responsibilities as well as investigator contracts, clinical operations and management of activities related to centralized laboratories (biopsies and blood samples). Activities for the study began even before a services agreement was signed with the sponsor because the new deadline was so tight; the new goal was to have randomized 100 subjects at the new sites by end of April 2009.

Our Solutions

SynteractHCR selected sites with which we had positive experiences completing a very similar previous trial. A special session was held during the investigators' meeting in December 2007 for anyone unfamiliar with Good Clinical Practice (GCP). SynteractHCR set up a clinical operation plan, approved by the sponsor, to shorten timelines as much as possible.

Administrative and regulatory aspects of the study needed revision because the study was planned initially to be run only in Italy. Several meetings were organized with the other national regulatory authorities to define the required documents for submission and administrative needs for biopsies, laboratory procedures, drug import, and biopsy deliveries. Investigator and hospital contracts were drawn up in two languages, requiring strict attention to detail and dedication from SynteractHCR administrative and financial staff.

The first site was initiated in Lithuania on July 15, 2008 and the first subject was randomized on August 6, 2008. Less than one year later the last patient in was randomized in a Russian site on April 20, 2009. SynteractHCR solved queries issued by data management, and the database was locked within the established deadline.

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Outcomes

All recruitment and timelines were reached by each country involved: 67 subjects were randomized in Russia, 28 subjects in Poland, and 12 subjects in Lithuania, for a total of 107 subjects, exceeding the original target of 100. The SynteractHCR team surpassed the sponsor's expectations with the last subject selection and enrollment. The database closure deadline was met with high quality, leading to good outcomes in both internal and on-site audits. Furthermore, the study reached the statistically significant result of the primary end-point. Sigma-tau executives appreciated the problem-solving capabilities and diligence of the project team, turning a problem project into a success.

"Flexibility, problem solving capabilities, understanding the Sponsor's needs, excellent communication flow, and creation of a collaborative and proactive environment from our SynteractHCR team translated a dying project into a success. Thank you."

- R. Camerini, M.D.
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