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

SynteractHCR worked cooperatively with client and sites to meet stringent project timelines

Introduction

The Chiesi Group, founded in 1935 in Italy, is developing and marketing innovative products in various therapeutic areas, and ranks highly among Italian investors in research and development within the pharmaceutical sector.

Recently, the company has focused on respiratory diseases, musculoskeletal disorders, and cardiovascular diseases.

SynteractHCR was awarded a project designed to assess the inspiratory flow profile through the Nexthaler® device in adult asthmatics with varying degrees of disease control, titled "The PIF Study". The study was a Phase IIa, single-center, open label, single-arm design study, and included 40 male and female patients (20 with controlled stable disease and 20 with partly controlled or uncontrolled disease) who were enrolled at the University Hospital in Parma, Italy.

SynteractHCR was managing study set-up and initiation (regulatory and ethics committee responsibilities, site contracts), clinical operations, pharmacovigilance, data-management, statistics and Clinical Study Report (CSR) finalization.

Challenges

The study deadlines were very tight. The study was delegated to SynteractHCR on 10 April 2012 and the first patient, first visit (FPFV) was planned on July 1, 2012 (3 months later). The last patient, last visit (LPLV) was planned for October 25, 2012 and final CSR on March 28, 2013. To meet these timelines, a quick ethics committee/competent authority (EC/CA) submission and efficient site recruitment was necessary to allow the next monitoring, data-entry and query resolutions to be done in time and within quality standards.

Our Solutions

SynteractHCR worked cooperatively with the client and site staff in order to meet the stringent project timelines. SynteractHCR began activities immediately, as soon as the power of attorney was signed, in order to meet the first available EC meeting (May 15, 2012). A preliminary technical meeting was completed with the client on April 5th to define strategies and create an action plan and EC submission was accelerated and completed on April 16th. SynteractHCR quickly planned the pre-trial visit (April 19th), the kick-off meeting with Chiesi (April 24th), and the investigators' meeting (May 16th), which included an added training for site staff on Good Clinical Practice (GCP). A contingency plan was set up to support CRAs since enrollment activities were scheduled during the summer.

SynteractHCR kept enrollment under tight control and put in place ad-hoc procedures for the study. These procedures included SynteractHCR team contacting the site regularly to ensure that enrollment was balanced and that the inhalation profile data was accurately saved and transferred.

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Successful Results

The PIF Study was a logistical and clinical success. All expected deadlines were met due to cooperation and proactive strategy at every trial stage. A dedicated team was able to complete final visit (FV) in four days and expedite EC/CA approval. LPLV was performed more than one month in advance of the expected deadline based on the well-established and collaborative relationship between the SynteractHCR team and site staff. This good working relationship continued throughout the study, and included granting full availability during vacation periods to avoid monitoring delays, case report form (CRF) cleaning, and data management.

The study met high quality standards and only minor findings were outlined during the on-site internal audit. No additional costs were incurred by the client and the study reached the result the client sought. Françoise Bonnet Gonod, Head of Late Phase Study Management at Chiesi CSM, says, "The SynteractHCR team was dedicated to the study from the start. The CRA developed a good relationship with the site staff and this was a large part of the study's success. The investigator was motivated to recruit and the timelines were met. The communication between Chiesi CSM and the SynteractHCR team was transparent throughout the study."

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