Accelerating Late Phase Study Enrolment

Dedicated expertise and advanced informatics to overcome study delays

Case Study

The Challenge

A large, multinational pharmaceutical company partnered with ICON to complete a Phase 3b/4 study to assess the efficacy and safety of an oral treatment for rheumatoid arthritis. The study randomised 1100 patients over age 18 with moderate to severely active rheumatoid arthritis, from 228 sites across 28 countries.

The study began as a split off from a larger exposure study, in October 2013. ICON and the sponsor collaborated on global footprint, site selection and timelines. Originally, 1080 patients were targeted from 237 sites in 29 countries across five continents, with enrolment planned to close at the end of 2015. By mid-2015, enrolment was behind globally due to competition from other studies with similar patient selection criteria. Significant regulatory delays in Germany, Hungary and Serbia also resulted in delayed site activation.

The Solution

ICON employed enrolment simulation models in conjunction with feasibility expertise to identify an improved, more robust strategy to meet enrolment timelines. The team decided to add sites in already approved countries. At the same time, ICON initiated an intense recruitment campaign, which included a study website, targeted seasonal postcards to sites, and a pharmacy referral program.

Last subject, last visit (LSLV) was advanced accordingly, which meant the new target for end of treatment phase coincided with the year-end holidays, which made patient visit scheduling and data entry by sites challenging. To overcome this, data cleaning was achieved using a batch strategy, whereby patients were assigned to a batch, based on when they were projected to have their last visit. The rolling deadlines for these batches helped to mitigate the large volume of data associated with the last patients enrolled, since almost 10% of patients entered the study within the last month of enrolment.

The Outcome

As a result of these efforts, enrolment was met in November 2015, more than one month ahead of target.

Capitalising on the time saved, the sponsor identified the possibility to aim for a late-breaking submission to the 2017 Annual European Congress of Rheumatology to help support the goal of product approval by the European Medicines Agency (EMEA). To meet the submission deadline, the team delivered results more than one month early.

Coordinated efforts across all functional lines within the sponsor and ICON enabled the team to successfully meet the stretch goals for LSLV, database lock, and reporting of results.

ICON's Value Add

The expertise of ICON's dedicated late phase team, combined with insights from our advanced clinical informatics, allowed the sponsor to overcome study delays and achieve enrolment earlier than planned.

- Nearly 400 late phase operational experts, 90 dedicated project directors, project managers, and clinical trial managers, working in 18 countries over 4 continents
- Immediate ability to query electronic health information on 70 million patients to support study design, site and patient recruitment
- Deterministic and stochastic recruitment modelling tools to project enrolment and assess probability of competing enrolment on time

The sponsor surpassed the original enrolment deadline, with sufficient additional time to submit study results for presentation at a key scientific conference, to further support this highly anticipated treatment.

For more information, contact:
enquiries@iconplc.com