

CASE STUDY

Refining Recruitment

Effective, Proactive Strategies Boost Epilepsy Trial

Study Description

A randomized, double-blind, parallel-group, placebo- and comparator-controlled multicenter study

Study Objectives

- > *To evaluate the study drug in reducing the frequency of partial seizure compared to placebo and comparator*
- > *To compare the safety and efficacy of the study drug to the comparator*

Study Compound

Gaba analogue

Patient Population

Adult patients with partial seizures without generalization

Treatment Period

Seventeen weeks

Primary Efficacy Parameter

Response ratio as a comparison of a baseline 28-day partial seizure rate with the double-blind treatment 28-day partial seizure rate

Study Specifics

- > *Active sites: 94*
- > *Patients randomized: 426*
- > *Recruitment period: 29 months*

Participating Countries

11 – Australia, Austria, Belgium, Germany, Netherlands, Poland, Portugal, Spain, Switzerland, United Kingdom, Canada

Quintiles Services

Project Management and Clinical Monitoring

Overview

At Quintiles, we have a variety of recruiting strategies at our disposal and the experience to implement them successfully. This study required the use of an assortment of approaches to reach the target population with enough coverage to recruit the specified number of patients.

Key Challenges

The customer had already actively recruited for six months before requesting assistance from Quintiles. The customer planned to continue to recruit the necessary 200 patients in Canada and asked Quintiles to recruit 226 patients from the other countries selected for the study.

The customer was having recruitment problems because the comparator was already marketed in the target countries and many of the prospective patients were receiving the drug. The protocol excluded any patient that received the comparator, the key concomitant medication, or benzodiazepines in the prior six months.

The study also required patients to complete diaries in a consistent way so that the information could be compared.

How Were These Challenges Met?

Strategic Expansion

Quintiles boosted recruitment by conducting a feasibility assessment in the existing countries and adding another 40 sites. In addition, Quintiles paid sites to undertake pre-screening.

To further enhance recruitment, the Study Site Coordinators screened the databases, contacted the Awareness of Epilepsy Association, and produced newsletters, competitive recruitment graphs, and advertising.

Motivational Support

To further enhance recruitment, the Study Site Coordinators screened the databases, contacted the Awareness of Epilepsy Association, and produced newsletters, competitive recruitment graphs, and advertising. Quintiles motivated the sites by holding dinner meetings with investigators to discuss issues and resolve problems and by asking CRAs to pay extra visits to the sites. Also, the customer visited the sites with the program director, the project manager, and the local head of clinical operations.

Ensuring Comparability

To ensure that the diaries were comparable, the sites trained the patients to use the customer's diary or allowed them to use their own, after which the Study Site Coordinators transcribed the information onto the CRFs.

Outcome

The customer was unable to reach its target in Canada, and so asked Quintiles to take over the Canadian recruitment. To the customer's delight, Quintiles achieved the Canadian target of 200 patients by recruiting 226 patients in 17 months.

Contact Us:

On the web: www.quintiles.com

Email: clinical@quintiles.com

