

Alzheimer's Disease: Engaging patients, caregivers and investigators

Therapeutic Area
Neuroscience

Indication
Alzheimer's Disease

Clinical Phase
Phase II

Participating Countries
2 - US, Canada

Study Details

- Number of active sites: 80
- Patients randomized: 640

PharmaNet Services

- Clinical monitoring
- Data management
- Medical Monitoring
- Medical Writing
- Pharmacovigilance
- Project management
- Regulatory Review
- Site management, contracts and administration
- Vendor management

Overview

A double-blind, Phase II, placebo-controlled clinical trial to evaluate the safety and efficacy of a novel compound in subjects with mild to moderate Alzheimer's disease.

Challenges

The challenges with this study mainly pertained to recruiting and retention of Alzheimer's patients, and the frequent reliance on caregivers to actively support the patients' participation. In addition, the length of the study was to exceed one year requiring long term strategies for patient and caregiver engagement.

The pipeline of new drugs for Alzheimer's disease can create an environment that is quite competitive for patients. In this case, the protocol had an extensive list of concomitant medications that were prohibited during the study making it more difficult to find qualified participants.

Solution

PharmaNet provided an ongoing analysis of screening trends from the sites, together with advice from PharmaNet's medical staff, allowing the client to re-evaluate inclusion/exclusion criteria. Based on actual enrollment data, the client was able to adjust the inclusion/exclusion criteria in the protocol which improved the sites' subsequent ability to recruit patients. PharmaNet also developed a multi-pronged approach that focused on site level logistics and the development of customized and effective recruitment tools.

- At the sites, an active and engaged relationship with investigators and open, ongoing communication contributed to the success of the clinical study project team. Training occurred throughout the study, beginning at the investigators' meeting and then reinforced during site initiation visits, planned periodic site teleconferences, and weekly site calls and reiterated in monthly newsletters.
- A variety of tools were deployed to assist in identifying qualified patients through a managed chart review. Specific strategies were also developed to engage caregivers. The caregiver program enhanced patient retention by providing caregivers with valuable information at each study visit that helped them understand and care for their loved one while showing them appreciation for their dedication to the trial.

Results

The difficult to recruit patient population was enrolled on time, the study milestones were met, and the study had an extraordinarily low query rate.

About PharmaNet

PharmaNet Development Group, Inc., an inVentiv Health Company and a recognized leader of global drug development services to the pharmaceutical, biotechnology, generic drug, and medical device industries, provides comprehensive capabilities in Phase I-IV clinical development, bioanalytical and bioequivalence services, regulatory, staffing, and therapeutic solutions. For the applied knowledge and intelligent solutions needed to accelerate drug development programs of all sizes around the world, *PharmaNet works for you.* For more information please visit www.PharmaNet.com.