

CASE STUDY

Anticipating the Challenge

Deep Alzheimer's Experience Accelerates, Eases Complex Trial

Study Description

A randomized, double-blind, placebo-controlled, Phase II study, and open-label treatment period of Alzheimer's patients

Study Objective

To evaluate the efficacy of a drug known to improve cognition in patients with mild to moderate Alzheimer's disease

Study Compound

Donepezil

Patient Population

Subjects with mild to moderate cholinesterase-naïve Alzheimer's disease

Treatment Period

14 weeks

Efficacy Parameter

Improved cognitive function assessed by CogState Computerized Neuropsychological Battery after 4-, 8- and 12-week treatment

Participating Countries

Hungary, India, Lithuania, South Africa

Study Specifics

- > Number of active sites: 26
- > Patients randomized: 106 (target was 100)
- > Recruitment period: 7 months

Quintiles Services

Project Management, Clinical Monitoring, Pharmacovigilance, Central Laboratories, Central ECG, Data Management, Regulatory

Alzheimer's disease: a universal problem.

Alzheimer's disease (AD), the most common form of dementia, is a progressive and fatal neurodegenerative disorder. According to estimates by the World Health Organization, about 18 million people worldwide have AD, a figure which is projected to nearly double by 2025. Much of this increase will be in the developing countries and will be due to the aging population.

Treating, tracking and testing

The following high-level background information is included to better explain this particular clinical trial case study:

- For mild to moderate AD, cholinesterase inhibitors are often prescribed to help delay symptoms or prevent them from worsening during a limited period of time.
- This study utilized an electronic case report form using data from several complex rating scales, including:
 - The Alzheimer's Disease Assessment Scale-Cognitive (ADAS-Cog), used to assess cognitive dysfunction in clinical trials via the patient's performance of 11 tasks.
 - The CogState Computerized Neuropsychological Battery, which measures changes in cognitive functions by comparing patients' functions after treatment or medication to their own "baseline" level of performance.

A complex trial multiplied by four countries

One key challenge for this clinical trial was recruiting a sufficient number of patients in an enrollment period that was shortened significantly (from seven months to four) in India and South Africa. A relatively small universe of cholinesterase-naïve patients, coupled with the existence of competing trials and the recruiting difficulties inherent in placebo-controlled studies, added to the recruiting challenge.

The primary issue, however, was the multiple complexities of the trial. The same caregiver, as well as the same rater, had to be available across all visits. Several assessment scales had to be performed at each visit, lengthening the time typically spent by a patient at the site. Finally – and most significant – was the specialized knowledge required to accurately assess the cognitive skills of the patients using the ADAS-Cog and the CogState Computerized Neuropsychological Battery.

Knowledge of the complexities of Alzheimer's disease and the assessment scales, along with experience in the countries chosen for the trial, enabled Quintiles to ramp up quickly and deliver results ahead of schedule.

Anticipation, preparation and communication

With nearly two decades of experience, along with a sophisticated understanding of the nuances of each of the countries involved, Quintiles was able to foresee the challenges posed by this trial and develop specific, detailed plans in order to address each of them. Sites were managed closely and proactively. Clear timelines and recruitment targets for each site and country were communicated frequently and progress was monitored continually. Recruitment tools were adapted according to what has historically proved most effective in each country. And doctors were thoroughly and carefully trained in the intricacies of the CogState rating system.

Extraordinary results

Thanks to the skills and experience of the Quintiles team with complex AD trials, including the rating scale and the electronic CogState Computerized Neuropsychological Battery, the milestones for FPI (First Patient In) and LPI (Last Patient In) were met ahead of schedule. In addition, all recruitment goals were achieved on time and the goal for randomized patients was exceeded. Screen failure and dropout rates were lower than anticipated.

In short, Quintiles delivered accelerated clinical and commercial outcomes

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