PPD®

Case Study

ALZHEIMER'S DISEASE

PROJECT BACKGROUND

PPD was selected to conduct project management, clinical and medical monitoring and safety activities for a Phase III program involving three studies that evaluated activities of daily living in subjects with mild dementia of the Alzheimer's type.

OBJECTIVES

The primary endpoint was to assess the change in cognition and activities of daily living as measured by ADAS-cog and ADCS-ADL in subjects with Alzheimer's disease treated with study drug.

Key secondary endpoints were to assess changes in cognition as measured by the Neuropsychological Test Battery and to assess changes in global function as measured by CDR-sb.

CHALLENGES

Within three months of enrollment, the sponsor implemented a protocol revision, which halted enrollment for two months, increased the number of sites by more than 40% and restricted the inclusion criteria to subjects with mild dementia (vs. original inclusion criteria to include mild to moderate dementia). Protocol revisions resulted in PPD's management of the largest Alzheimer's trial conducted in the U.S. to date.

In addition, the participating sites were unfamiliar with the fax-based data management system, which was perceived as cumbersome and inefficient. As a result, just six months prior to completion of study participation over 8,000 queries were outstanding, threatening project milestones. High-level metric reports provided insufficient detail to pinpoint root causes.

STRATEGY

PPD worked closely with the client to determine the root cause of data management problems. PPD then developed standard processes and new reporting formats for transparent interim reporting, enabling queries to be identified and resolved more quickly.

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RESULTS

- *PPD's simple but effective strategy of structured conference calls with all participating sites not only boosted enrollment, but provided the necessary motivation to sites during a critical stage of the study.*
- *PPD's revised data management approach reduced queries by 75%.*
- *PPD was able to transfer these practices to the global study which commenced a year later. As a result, the screen failure and early termination rates were reduced by 5% and 10% respectively, and the number of queries issued was reduced by 60%.*

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STRATEGY

The protocol revisions presented significant enrollment challenges in addition to unique challenges associated with site motivation during the unexpected "down time." In an effort to keep sites engaged and motivated, PPD held regular conference calls with all participating sites to assess performance, share best practices and address questions related to ongoing issues. Information-sharing on a regular basis included:

- High-enrollers success strategies
- Interim results from an ongoing Phase II study
- Updates on safety information
- Data management training for revised procedures