VERISTAT

Clinical Development Support for Multiple Alzheimer's and Parkinson's Studies

How a Responsive Clinical Operations Partnership Ensured Seamless Trial Management

Background

A clinical-stage biopharmaceutical company approached Veristat after experiencing challenges with its previous CRO. The sponsor was developing a small-molecule compound for both Alzheimer's and Parkinson's disease indications. As a small company with limited clinical trial experience, the sponsor required a responsive CRO partner that could provide both strategic expertise and hands-on guidance throughout their clinical development program. Veristat was engaged to rescue the trials from the previous CRO, providing comprehensive services including site management and monitoring, medical monitoring and safety management, project management, and remote trial services.

STUDY DEMOGRAPHICS

INDICATIONS/PHASES

- Alzheimer's disease (Phase 2/3; two parent studies with open-label extension, 150+ sites)
- Parkinson's disease (Phase 2; one study, 10 sites)

SITES

- Multiple sites across the United States and Australia

PRIMARY SERVICES PROVIDED

- Clinical Monitoring & Site Management
- Medical Monitoring & Safety Management
- Remote Trial Services
- Project Management

Challenges and Solutions

Challenges	Solutions
Transitioning the TMF from a previous CRO system into Sponsor's platform required setup, alignment, and gap analysis	Veristat's Study Management team led the transfer, implemented a new TMF plan, and ensured progress with weekly status calls
Program rescue from previous CRO with communication and management issues	Implemented new communication protocols and clinical monitoring plans to ensure responsive and proactive management, including holding weekly leadership-level meetings
Client needed extensive guidance as a small company with limited clinical trial experience	Provided hands-on support, shared SOPs, and offered continuous guidance throughout trial execution
Database design issues inherited from the previous CRO	Worked with the existing database structure to optimize data cleaning and preparation for analysis, supporting unusually frequent interim analyses and continual data cleaning, which required disciplined internal timelines and proactive planning to manage operational complexity
Need for efficient monitoring across multiple sites	Implemented a hybrid monitoring approach, alternating between on-site and remote visits based on enrollment status and site needs
IP accountability requiring careful management	Prioritized on-site visits for high-enrolling sites to ensure proper IP accountability

Program Overview

The comprehensive program included two randomized, double-blinded, placebo-controlled studies for the treatment of Alzheimer's Disease and an extension study that allowed participants from the previous studies to receive active treatment. The Sponsor sought an additional indication of Parkinson's disease and Veristat supported them in their Phase II trial.

In the Parkinson's global study, Veristat successfully initiated the study, enrolled approximately 28 participants, managed monitoring visits and close out for 10 sites.

For the two randomized Alzheimer's studies, Veristat successfully transitioned the program from another CRO and managed the activation and ongoing support of more than 90 sites across the US and Australia, overseeing enrollment through closeout of over 500 patients—a significant operational achievement given the studies' size and complexity.

Both programs progressed into extension phases, with 75 sites continuing participation and more than 400 patients rolling over, further demonstrating Veristat's ability to manage large, multi-site clinical programs effectively. Unfortunately, results showed that neither the trial's primary endpoint nor its key secondary endpoints reached statistical significance compared with placebo; therefore, the studies were terminated.

Impact

Although the clinical program did not meet its primary and secondary endpoints across the studies, Veristat provided the responsive, expert support the Sponsor needed.

- Successfully managed the Alzheimer's studies until close out
- Implemented an effective hybrid monitoring approach
- Maintained open communication throughout the program
- Adapted quickly to study changes and early terminations

The Alzheimer's studies were impacted by a strong placebo effect, leading to early termination of the studies. Exploratory analyses suggested potential signals of benefit in certain subgroups and biomarkers, though a statistically significant advantage over placebo was not demonstrated. Despite the disappointing clinical outcomes, which are not uncommon in challenging indications like Alzheimer's disease, Veristat's responsive approach and expertise demonstrated the value of a flexible, hands-on CRO partnership that can adapt to changing circumstances while providing personalized attention to sponsors with limited clinical trial experience.