CASE STUDY

Applying a patient- and site-centric approach in an early Phase I Alzheimer's disease study

Advancing clinical research in Alzheimer's disease (AD) is inherently complex but a critical component for gaining new understanding about how to treat the disease or slow/prevent its progression. This case study discusses how Fortrea applied creative problem-solving to work through inherent challenges and shares a unique enrollment strategy for supporting sites and patients.

Recognizing the challenges

Enrollment in Alzheimer's disease studies is lengthy and complicated	Like many other AD studies, this trial required numerous clinical visits with lengthy cognitive assessments and cerebrospinal fluid (CSF) sampling on patients with mild cognitive impairment due to AD or mild to moderate AD.
Many eligible patients for the first cohort were awaiting enrollment	In the Phase I setting, every patient counts. Eligible patients who have committed to these early phase trials are extremely valuable. Leaving these patients behind would jeopardize their enrollment for future cohorts or future trials.
Study progress was unpredictable	With a cohort escalation based on toxicity, the team needed to balance the timing while ensuring safety and efficiency.

KEY TAKEAWAYS

With proactive, out-of-box thinking in this early Phase I multiple dose, dose-escalation study, the Fortrea team:

- **Completed enrollment for the second cohort within one week**
- **Completed full enrollment three weeks early and enrolled all eligible patients**
- **Delivered sufficient data from first two cohorts, enabling the Phase II Proof of Concept (POC) study to start earlier than planned**

Fortrea

Employing a patient- and site-centric approach

Applied an innovative approach to ensure all eligible patients were included

To maintain engagement with patients who had been screened for the first cohort but were not yet enrolled, Fortrea created a virtual waiting room. These patients were prioritized and re-screened, if necessary, as soon as an opening in the next cohort was available.

Developed communications to keep the sites engaged

The team employed advanced tactics more commonly used in late-phase trials, such as monthly meetings with all sites, monthly status emails and a personal letter from the joint sponsor-Fortrea team.

Supported healthy relationships between the sites and patients

After a cohort was filled, patients were given equal opportunities to participate in the study through a lottery across the sites. This coordination helped maintain the essential relationships between the investigator and each patient.

Deployed an effective centralized enrollment strategy

Fortrea launched a comprehensive enrollment strategy by listing the study on centerwatch.com, Join Dementia Research, as well as clinicaltrials.gov. This level of outreach, which is not typical for early Phase I trials, led to high enrollment.

Enabling a successful collaboration

By keeping the patients at the center of the Alzheimer's disease study—from planning through close-out—Fortrea enabled effective enrollment and fostered productive relationships between the site and patients. Active site engagement helped enhance recruitment efficacy and promoted study execution.

The sponsor appreciated the innovative approach and management applied by Fortrea. As a result, they awarded Fortrea additional work to support similarly designed programs in several other therapeutic areas.

Apply our scientifically rigorous patient-centric strategy to reduce the participation burden and increase the value of your neuroscience study.

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