perceptive imaging

Case Study

Rapid Scale-up of Imaging Services for Phase 3 Alzheimer's Clinical Trial

Background

Perceptive was selected by one of the world's leading pharmaceutical companies to provide clinical trial imaging services for a phase 3 study assessing the safety, tolerability, and efficacy of a novel, amyloid plaque-targeting therapy for Early Symptomatic Alzheimer's Disease (AD). The compound was designated a breakthrough therapy by the FDA, meaning that we would have to meet the operational, regulatory, medical, and scientific demands to help the sponsor achieve their accelerated development timelines.

The sponsor's protocol relied on medical imaging as an objective, noninvasive biomarker that enabled:

- **Patient population characterization:** The sponsor had specific enrollment processes that required the screening of subjects with reads and analytics
- **Longitudinal assessment of disease modification:** One of the treatment goals of the study was to see the change in brain amyloid plaque deposition from baseline through Week 76 as measured by amyloid positron emission tomography (PET).
- **Treatment decisions:** If PET scans revealed participants were confirmed to have reached minimal amyloid plaque levels, they were able to complete treatment and switched to placebo for the remainder of the study.

Challenges

This study presented numerous challenges, including that the sponsor needed to have an imaging core lab solution in place within a few months of engagement. The sponsor planned for accelerated enrollment rates, which required a significant number of sites to be onboarded and the imaging database and workflows completed in record time.

The study would become one of the largest phase 3 Alzheimer's disease clinical trials, lasting 30 months and involving 1,736 enrolled subjects at 390 investigative sites across the USA and Europe. Rapid turn-around-times (TATs) of PET eligibility reads and analysis were essential for quickly enrolling subjects and meeting the sponsor's accelerated development timeline.

Key Highlights:

- Over 390 sites onboarded in < 3 months
- ~6,900 eligibility scans reviewed over 7 months
- Average > 100 scans/day at peak
- Query response TAT = ~1 day
- Eligibility scan reviews TAT = ~2-4 days
- 1,736 enrolled subjects
- 30-month trial
- ~9,000 Amyloid PET scans and ~4,500 Tau PET scans reviewed

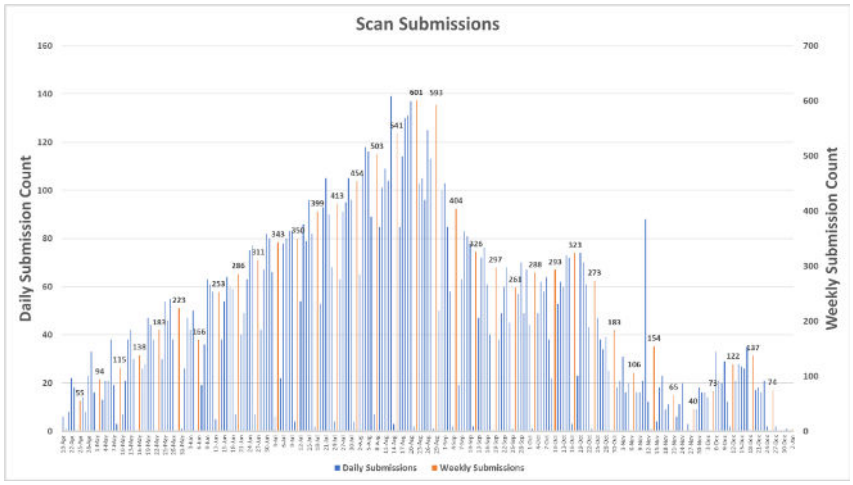
Perceptive's ability to quickly scale led to the approval of a novel treatment, giving patients more options in an area with a significantly unmet clinical need.

Perceptive Delivered

Having supported over 260 AD trials to date, Perceptive Imaging was ready for the challenge. We had the right people, processes, and technology to perform the reads and quantitative analysis the sponsor needed, so we hit the ground running.

This was an "all hands-on deck" approach by the team, working closely and collaboratively with the sponsor. Following our established, global operational processes, we efficiently trained investigative sites on image acquisition and prepared our wide AD reviewer network to begin conducting image reads in accordance with the imaging charter.

By doing so, Perceptive met the sponsor's accelerated timelines, onboarding over 390 sites in less than three months, which enabled the continuation of enrollment as planned.



During seven months of enrollment, our AD imaging scientists and reviewer network performed the reads and quantitative analysis of over 6,900 eligibility scans (averaging > 100 scans / day at peak enrollment) as dictated by the study-specific charter. Our imaging core lab team closely monitored images to ensure timely workflow progression and delivery of results within the targeted TAT. Our reviewers effectively analyzed and returned results within approximately 2-4 business days, enabling the sponsor to meet their accelerated enrollment targets.

Using our imaging platform, Perceptive oversaw and performed the imaging reads of ~9,000 Amyloid PET scans and ~4,500 Tau PET scans.

Results

The imaging data from the phase 3 trial demonstrated the compound's effectiveness at reducing amyloid plaques and significantly slowing clinical decline among study participants. In 2024, this novel compound was granted FDA approval for the treatment of early symptomatic Alzheimer's Disease, which includes mild cognitive impairment and the mild dementia stage of Alzheimer's disease, with confirmed amyloid plaques.

This approval represents real progress in the field of Alzheimer's Disease, giving patients more treatment options and a greater opportunity to live longer, fuller lives.

Contact hello@perceptive.com to discuss your Alzheimer's Disease program and learn how Perceptive Imaging can help you meet your clinical development objectives.