CASE STUDY

Clario supports large pharmaceutical company with a complex Alzheimer's disease study

A ground-breaking treatment gains accelerated FDA approval

Challenges with global Alzheimer's disease trials

Developing drugs that have been able to slow the progression of Alzheimer's disease (AD) and conducting successful trials have been notoriously difficult for sponsors.

AD is a complex neurological disease that poses multiple challenges for sponsors. These include determining the correct imaging endpoints to acquire and analyze, correctly diagnosing patients and managing side effects of drugs.

To provide the necessary safety and efficacy evidence to regulators, a large quantity of highly precise and standardized MRI, PET and ECG data across a wide patient population is needed.

To overcome these challenges, it is vital to choose a provider who has deep neuroscience expertise, at-scale data collection and analysis capabilities and global deployment experience.

Situation

Over the last 10 years, a large pharmaceutical sponsor has been evaluating a novel AD treatment in Phase I to III trials. This ground-breaking treatment has shown to be effective in slowing the progression of early-stage AD.

The study has taken place in 15 countries across North America, Europe and APAC.

Clario has supported the sponsor over all three phases throughout this period to ensure the highest quality imaging and cardiac safety data for FDA submission.

Summary

- A ground-breaking AD treatment gained accelerated FDA approval in 2023.
- Supporting a large pharma company over Phases I to III, Clario provided robust and standardized imaging and cardiac safety data for FDA submission.

Clario neuroscience experience

- ✓ 20+ years of AD and related dementias experience
- ✓ 600+ neuroscience studies
- ✓ 90%+ of Phase III AD trials with imaging endpoints performed by the team
- ✓ Unmatched experience in both MRI and PET imaging, with extensive amyloid-related imaging abnormalities (ARIA) monitoring expertise

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Clario solution

Clario has provided the scientific, technical and operational support for imaging and cardiac safety data collection across a range of safety and efficacy endpoints, including:

- Standardization of imaging data acquisition.
- Qualification of all imaging equipment and training of site staff.
- Collection, quality control, blinded central review/ analysis and overall data management of over 35,000 MRI and amyloid PET time points from over 1,200 sites, along with over 20,000 ECGs.
- Review of imaging-based inclusion and exclusion criteria shortly after image acquisition.
- Centralized safety monitoring of ARIA and other MRI abnormalities.
- Centralized quantitative analysis (volumetric MRI and amyloid PET SUVR).
- Centralized ECG review by ECG technician and cardiologist.
- Training of site staff.

Clario has supported the trial lifecycle from protocol development to FDA submission.

Impact

Support for accelerated FDA approval

- Following the success of the Phase III trial, the FDA granted accelerated approval in 2023.
- Clario's disciplined approach provided robust and standardized evidence to demonstrate the drug's safety and efficacy.

Ongoing support with FDA submission and industry education

- Clario is now supporting the sponsor gain full FDA approval.
- Clario's expert scientists are helping to educate the industry on detecting adverse events (ARIA) in a clinical setting.

Clario's key success factors

Clario's science-led approach has involved:

Neuroscience expertise

- Complex diseases require experienced scientific guidance throughout the trial.
- Clario has an expert team of scientists, neuroradiologists and cardiologists who support areas including:
  - Determining the correct endpoints.
  - Reviewing participant inclusion and exclusion criteria.
  - Monitoring and reporting side effects (ARIA).

Robust and standardized data collection at scale

- Clario follows the highest quality standards and processes for standardized image acquisition, training, data collection, quality control and centralized analysis on a global scale.
- Clario's approach has ensured the highest quality data for regulatory submission.

Global trial support

- The Clario team qualified over 1200 MRI and PET sites.
- The Clario team shipped a large volume of standardized ECG devices to over 250 sites.
- The interactive Clario Study Portal provided full visibility to the sponsor to monitor progress of the trial.

Our team of experts is ready for your questions about your next neuroscience clinical trial. To contact us, go to clario.com/therapeutic-areas-page/neuroscience or email info@clario.com.

Clario generates the richest clinical evidence. Fusing our deep scientific expertise and global scale into the broadest endpoint technology platform, we empower our partners to transform lives.