

Infusion and Follow Up at Home for Pre-Clinical Alzheimer's Global Home Visits Exceed Expectations in a Challenging Study

BACKGROUND

Alzheimer's disease is an age-related neurodegenerative disorder characterized by progressive decline in cognitive function and the ability to perform activities of daily living, ultimately resulting in dementia with fatal complications. Evidence suggests that the pathophysiological process of Alzheimer's begins well more than decade before the clinical stage now recognized as Alzheimer's dementia, and that neurodegeneration is already apparent by the stage of mild cognitive impairment.

SITUATION

This Phase 3, adult participants, clinical trial was focused on pre-clinical Alzheimer's disease and required a one-hour intravenous infusion every month for 4.5 years during the double-blind treatment period with the option for an additional 4 years during the open-label treatment period. The COVID-19 pandemic impacted the delivery of elective health services making it difficult for participants to continue monthly infusions. The only way for this trial to retain some of its participants was by implementing decentralized clinical trial methods including mobile research nurses to execute home visits.

HOME VISITS FOR CLINICAL TRIALS

PCM Trials was selected as the mobile research provider for this study to overcome barriers to treatment during COVID-19. The PCM Trials nurses are direct employees and Certified Mobile Research Nurses (CMRNs), increasing the quality of care provided to the participant and improving quality of data reported to the site. The PCM Trials project management team was responsible for the coordination of IP delivery and ancillary infusions supplies which separates the logistical responsibilities from the clinical responsibilities, allowing the CMRNs to focus on the participant and clinical visit objectives.

The study has since implemented home infusions as an option to participants other than COVID-19 mitigation illustrating the many advantages of home-based clinical trials including:

- Increased convenience for participants by minimizing potential burden associated with site visits
- Improved adherence to protocol and compliance
- High cost-savings compared to trials conducted at a clinical site
- Expanded geographical reach and increased enrollment numbers
- Improved recruitment and retention of more diverse patient populations

THERAPEUTIC AREA
Neurodegenerative Disorder

DIAGNOSIS
Pre-Clinical
Alzheimer's Disease

CLINICAL TRIAL
Double-blind, Randomized
Phase 3 Study

DURATION OF TREATMENT
4.5 Years

IP DELIVERY
Intravenous Infusion

COUNTRIES
3

SITES
24

PARTICIPANTS
120

SUCCESSFUL HOME VISITS
900+ in 1.5 years

PLANNING A FUTURE TRIAL? In-home visits for clinical trials are no longer just an option—they are essential. Contact us today at info@pcmtrials.com and [+1.303.253.7470](tel:+13032537470).