

# Decentralized Trial Meets Aggressive Timeline and Budget with Firma's Patient-Centric Home Health Trials



**DURATION:**  
**6 Months**



**TOTAL PATIENTS REFERRED:**  
(Via Registry)  
**1,185**



**ELIGIBLE PATIENTS CONSENTED:**  
**854**



**ELIGIBLE PATIENTS PARTICIPATING:**  
**854**



**VISIT FREQUENCY:**  
Single Blood Draw



**COUNTRY:**  
US

A leading diagnostics company was researching the association of specific biomarkers to indicate the likelihood of early onset Alzheimer's Disease. The trial involved collaboration with a well-regarded University and use of their national patient registry. Firma was engaged to support patients on this decentralized trial when the original home trial service provider (HTP) was unable to meet the geographical oversight, patient engagement, and timeline needs of the Sponsor. With Firma's support, the Sponsor achieved their trial goals and timelines on this decentralized trial.

## STUDY CHALLENGES

While blood draws are common amongst investigational protocols for home health trials, this study presented several interesting challenges, including being a decentralized/site-less trial, aggressive timelines given delays with previous vendors, and complex in-home blood sample processing. Firma was given a goal of sourcing 550 samples and a timeline of just six months to complete everything from the informed consent to completion of sampling and data collection.

### 1 NO SITES

As a completely decentralized trial, there would be no sites and therefore no Principal Investigators normally associated with those sites. Firma was responsible for leading and ensuring the eligibility of participants as well as a fully compliant informed consent process. Firma contacted 1,185 potential patients to review the study details. Given the Alzheimer's Disease indication, these discussions involved the patients as well as their caregivers.

### 2 AGGRESSIVE TIMELINES

Firma was engaged later in the process—after the originally selected home trial service provider (HTP) was unable to meet the geographic coverage and support needs of the trial—resulting in an aggressive timeline for project completion. In addition to this late trial introduction, the Firma team also needed to work efficiently to coordinate additional and separate agreements with the University to gain appropriate data access prior to patient outreach.

### 3 COMPLEX BLOOD PROCESSING & TRAINING

Each of the 674 home health visits included an intense and complex on-site blood processing protocol. To meet the critical sample integrity needs, and with just one chance to collect samples from each patient, every trial needed to be of high-quality. To that end, in addition to our comprehensive standard protocol training, the aligned Firma team also deployed additional, more intense video training sessions and incorporated them into team training at no extra expense to the diagnostics company.

#### RESULTS

More than 72% of referrals consented to participate and nearly **80% of all patients who consented ultimately participated in the trial**, due in large part to Firma's patient-centric approach. Consent engagement and interest was high, and participation was enhanced with Firma's patient-centric approach to visit scheduling, with most patients citing direct preference for a visit within 14 days of the consent call. Respecting and integrating the preferences of these patients clearly resulted in their high participation rate and in benefit to their experience and the trial research.

**Sample integrity was very high.** Ensuring technicians were sufficiently trained created an exceptionally diligent collection process. Both Firma's standard comprehensive process and the supplemental video training to this specific clinical trial protocol resulted in high-quality data used for analysis—especially important given the biomarker analysis sought on this trial.

**Firma completed the trial under budget and well within the timeline.** The Firma team worked efficiently across the trial as a whole and was able to deliver additional cost savings to the Sponsor by geo-clustering health providers when possible. This approach allowed Firma to support the largest number of patients with the most focused number of highly trained providers. As a result, the Sponsor was able to reallocate the budget savings to increase the overall samples collected within the revised timeframe.

This study will be presented at the Alzheimer's Association International Conference (AAIC) in July 2019.

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# 674

VISITS IN  
6 MONTHS

# 97

HEALTH  
PROVIDERS  
TRAINED

# 79%

PATIENT  
PARTICIPATION  
RATE

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