VIRTUAL

Decentralized Alzheimer's Diagnostic Clinical Trial Meets Aggressive Timeline with Firma – and Finds Promise in Simple Blood Test

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

Predicting Alzheimer's disease in patients – in advance of symptoms – is not easy. To date, physicians either need to perform a spinal tap or a PET CT scan. The former is both invasive and painful, the latter, while less involved, is still prohibitively expensive running anywhere from $6,000-$10,000. C2N Diagnostics is a leading diagnostics company developing state-of-the-art analytical technologies for identifying and quantifying blood-based biomarkers for neurodegenerative disorders, with a current focus on biomarkers specific for Alzheimer's disease pathology.

"There is a critical need for a simple predictor like a blood test – something that correlates with the accumulation of amyloid plaques in the brain," said Kevin Yarasheski, PhD, senior vice president at C2N Diagnostics.

The company developed such a test, but validating the test in an appropriately conducted clinical trial presented a number of challenges. This group of patients had some level of dementia and traveling to a Clinical Site for a blood draw would have been burdensome.

"We wanted to relieve this burden and have the patients remain in their homes. But we had real trouble finding a company willing and, quite frankly, able to meet the requirements for a decentralized blood collection – and the timeline," said Yarasheski. "I got a lot of 'no's' from home visit companies until I got to Firma. They said, 'That's exactly what we do.'"

Firma was given a goal of collecting around 500 blood samples in participants' homes and a timeline of just six months to complete everything from the informed consent to completion of blood sampling and data collection.

Meeting Study Challenges

While blood draws are common among investigational protocols for home health visits, this study presented several interesting challenges, including being a site-less (aka virtual) trial, aggressive timelines due to the nature of the study protocol, patient cohort, and complex in-home blood sample processing requirements.

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No Sites

As a completely decentralized trial, there were 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 potentially eligible patients to review the study details. Given the Alzheimer's disease indication, these discussions involved the patients as well as their caregivers. And it was blinded research so Firma had to explain they wouldn't be getting the results of the test – a situation that can significantly impact recruitment success.

More than 72% of referrals consented to participate, and nearly 80% of all patients who consented ultimately participated in the trial. Additionally, Firma's patient-centric approach to visit scheduling respects and integrates the preferences of the patients, so most patients opted for an in-home visit within 14 days of being found eligible for the trial. This was critical, because Firma needed to collect blood samples from each patient within several months of their amyloid PET CT scan. Firma was working against a rapidly approaching deadline because the window of opportunity for blood collection was quickly closing.

Aggressive Timeline

Potentially eligible participants were identified from a secure centralized database and their contact information shared with Firma, so C2N Diagnostics remained blinded to all identifiable and health-related patient information. Prospective participants had recently received an amyloid PET CT scan that determined whether amyloid plaques were present or absent in their brain. In order to validate their blood test, C2N biostatisticians needed to compare the blood test results to the PET CT image results and calculate the accuracy of the blood test.

"If Firma didn't contact, consent, enroll and obtain blood samples from the patients before June 2019, all potentially eligible patients would have disqualified," recalls Yarasheski. "Firma had to work very quickly to meet the aggressive enrollment requirements."

Complex Blood Processing and Training

Each of the 674 home health visits included an intense and complex on-site blood processing protocol. Blood draws might be a common investigational protocol for home visits but, in this case, processing needed to happen immediately following collection and required a level of skill and attention to detail beyond the usual home health tasks.

The biomarkers degrade quickly so home visit nurses would need to centrifuge the blood in-home within 30 minutes of collection, freeze the plasma samples within an hour, and ship appropriately to arrive at C2N Diagnostics within 24 hours.

VIRTUAL

674

VISITS IN 6 MONTHS

97

HEALTH PROVIDERS TRAINED

79%

PATIENT PARTICIPATION RATE

To meet the critical sample integrity needs, and with just one chance to collect samples from each patient, every visit needed to be high-quality. So, in addition to Firma's standard comprehensive protocol training, the aligned team deployed additional, more intense video training sessions and incorporated them into team training at no extra expense to the diagnostics company.

"I was amazed by how quickly Firma identified the in-home nurses with the right level of skill, and trained them to the protocol," said Yarasheski. "We contracted with Firma in September and, by October, blood samples were already arriving at our lab."

Firma also provided a level of oversight Yarasheski hadn't expected. Within the first month, they identified a couple of home health providers who consistently submitted lower quality samples, traveled to their location, and gave the team in-person training.

The result: Sample integrity was exceptionally high.

"No matter how many you collect and ship, if samples are poor quality – if they thawed or weren't properly centrifuged – then the visits would be useless," said Yarasheski. "Firma didn't just deliver quantity, they delivered quality. "

Ensuring technicians were sufficiently trained created a critically diligent collection process. The supplemental video training to this specific clinical trial protocol resulted in high-quality data used for analysis – especially important given the biomarker validation sought on this trial.

A Quality Partnership

Firma completed the trial under budget – and early.

Working efficiently across the trial as a whole, Firma was able to deliver cost savings by geo-clustering health providers when possible and support the largest number of patients with the most focused number of highly trained providers.

As a result, C2N was able to reallocate the budget savings and increase the number of samples collected all within the original timeframe.

"It was not an easy protocol. Firma managed to consent 600 out of over 1,000 potentially eligible patients, they completed everything early and the samples were quality," said Yarasheski. "Firma not only said they could do it, they actually did it."

Best of all, the preliminary results suggest there is concordance between the blood test results and the amyloid PET CT image results – further validation of this observation is ongoing at C2N Diagnostics.

"Without Firma's home visit option, I'm not sure this clinical trial would have even been possible," said Yarasheski. "Firma was as invested in the successful completion of this study as we were and that made them a remarkable partner."

That the results may lead to new diagnostic options for patients, while not inevitable in all clinical trials, is a gratifying reward for a job well done.

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