SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

CASE STUDY:

SIGNANT SMARTSIGNALS ELECTRONIC CLINICIAN RATINGS

OVERVIEW:

A global pharmaceutical company sought to implement remote clinical ratings in a multinational Alzheimer's disease study, in response to movement restrictions placed by the COVID-19 pandemic.

TRIAL SUMMARY:

Study Phase: Phase III

Therapeutic Area: Neurology

Indication: Alzheimer's Disease

Participant Population: Elderly adults

Number of Subjects: 1,800+ patients

Number of Sites: 150+ sites

Countries: 10+ countries

CHALLENGES:

01

ENSURE CONTINUED TRIAL OPERATION DURING COVID-19 PANDEMIC

The study was designed to include site visits for investigators to perform face-to-face clinician ratings to assess Alzheimer's disease status, including assessments such as the ADAS-Cog* and MMSE*. The sponsor asked Signant for a rapid solution to continue these assessments remotely and enable the study to continue without patients needing to attend site visits.

02

ENSURE CONSISTENT CLINICIAN RATINGS WHEN MIGRATING TO REMOTE ASSESSMENTS

Clinician ratings comprised primary and secondary endpoints, and ensuring the accuracy and reliability of these when migrating to video-assisted assessments was paramount. The sponsor sought clinical and scientific expertise from Signant experts to ensure the new method of assessment provided ongoing data that the study team could rely upon.

03

NEGOTIATE TECHNOLOGY LITERACY CHALLENGES IN ALZHEIMER'S PATIENTS AND THEIR CAREGIVERS

Alzheimer's patients and their caretakers may have difficulty setting up and operating hardware needed for video assessments at home. Signant was asked to work with a home nurse provider to ensure assessments could be completed as needed.

SOLUTIONS:

01 IMPLEMENTATION OF A SOLUTION TO CONDUCT VIDEO-BASED CLINICIAN RATINGS

Signant rapidly implemented a telemedicine solution to enable secure and compliant video consultations between the investigator and patient. We provisioned and distributed tablet computers to a mobile nurse network and provided training on how to set up and oversee video consultations in the patients' homes.

02 THOUGHTFUL MIGRATION OF FACE-TO-FACE CLINROs TO VIDEO ASSESSMENTS

Our in-house clinical science experts helped to adapt and migrate ClinRO assessments, working with scale authors when needed, to an electronic format while ensuring ongoing endpoint reliability and accuracy. Additional training was provided to investigators to ensure video ratings were performed in way that standardized administration and scoring techniques, mitigated inter- and intra-rater variability, and managed placebo response. Rating interviews were also captured to allow central raters to assess the quality and accuracy of ratings on a continual basis. Data scientists provided additional analytical services to assess and mitigate ongoing endpoint quality.

03 EQUIPPING HOME NURSES TO FACILITATE HOME ASSESSMENTS

Screening, baseline, and end-of-trial visits were still conducted at sites, while kits were provided to mobile nurses to help them facilitate ClinRO assessments from the comfort of participants' homes, supported by the video-based technology Signant provided.

ABOUT SIGNANT HEALTH

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Signant Health is the evidence generation company. We are focused on leveraging software, deep therapeutic and scientific knowledge, and operational expertise to consistently capture, aggregate, and reveal quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 20 years, over 400 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, eConsent, RTSM, supply chain management, and data quality analytics. For more information, please visit www.signanthealth.com.