

Novel remote visit approach in Japan paves the way for a patient-centric ALS clinical trial, enhancing recruitment success

A KEY QUESTION



How can you effectively establish and implement a new in-home clinical service for amyotrophic lateral sclerosis (ALS) in a country with limited prior exposure to mobile clinicians?

KEYWORDS

Mobile Clinical Services (MCS), Amyotrophic Lateral Sclerosis (ALS), Patient Engagement, Clinical Trials in Japan, Biotech

A biotech company with a global Phase II amyotrophic lateral sclerosis (ALS) trial needed solutions to reduce the burden of their clinical trial for patients. Due to the challenges associated with ALS, any reduction in travel to investigator sites would be beneficial and could increase patient engagement, reduce the potential for dropout, and even potentially accelerate enrollment in the trial. At the time the trial was being designed, it was uncommon to include in-home services for clinical trials in Japan; in fact, a **recent survey** there has shown that some participants, particularly elderly subjects, might be more apprehensive about bringing mobile clinicians into the home.

Fortrea partnered with the client to overcome significant challenges in contracting and implementation. Because this was our first application of Mobile Clinical Services (MCS) in Japan, many setup aspects were novel to the parties involved. The collaboration among the sponsor, Fortrea, and the sites required extra attention due to the novelty of the service in this geography. Execution of site agreements to include the use of MCS required special care and attention to ensure all stakeholders, including the non-Fortrea contract research organization and central laboratory, were prepared to facilitate compliance with local regulations and the protocol specifications. Fortrea MCS is adept at working collaboratively in complex situations such as this, with a dozen years of experience supporting sponsors who use a variety of vendors.

Fortrea MCS was able to offer regionally tailored solutions appropriate for this ALS study, including administration of investigational product subcutaneously via an ambulatory infusion pump, training patients and caregivers in trial procedures, and the collection of blood samples during the in-home visits. The protocol specified up to two at-home visits per patient over the course of the trial.

This trial is being conducted in 18 countries, with a total of 65 investigator sites. Japan has a large share of the sites, with **13 sites in Japan** included in the trial.

Of these 13 sites,
**10 have opted to use Mobile Clinical Services
(MCS) from Fortrea**
to benefit their patients

With the trial nearly complete, in the approximately one-year duration of the Phase II trial, a total of 10 patients have participated in MCS visits, with a total of 19 visits occurring during this period ending in October 2022. This was Fortrea's first use of MCS in Japan, and feedback from patients and investigator sites has been positive. The sponsor has initiated a change order to extend the contract to include three more visits per patient, allowing our collaboration to continue into the future.

LEARN MORE at fortrea.com