Accellacare

In-Home Services

Expanding geographic reach in rare disease study

Case study

The challenge

A small pharmaceutical company was conducting a Phase II study to evaluate the safety, efficacy and tolerability of an oral study drug to be taken twice daily. The study was targeting 32 adult patients (16-60 years old) with an inherited rare neurodegenerative movement disorder. The patients' symptoms included gait disturbances, speech problems and heart disease. As the disease progressed, many subjects required wheelchairs and were relatively immobile due to extremity paralysis. Due to the rarity of the disease, patients were geographically dispersed and as only one investigative site was opened in the US this often required travel which proved a burden to patients. Consequently patient enrolment was slow and the sponsor required an alternative solution to boost recruitment.

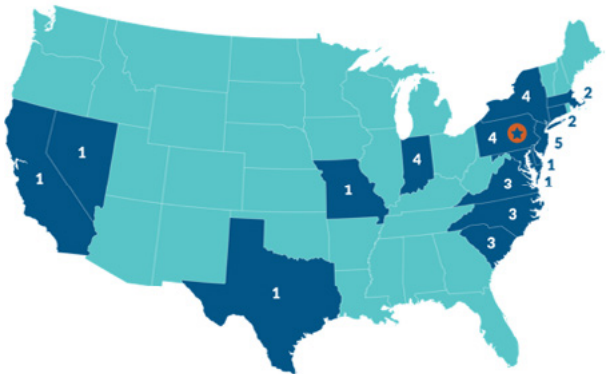
The solution

Accellacare In-Home Services (formerly Symphony Clinical Research) was contracted by the sponsor to conduct seven of the eleven required weekly visits, significantly easing patients' travel burden. In-home visit activities included peripheral blood draws, centrifuging, packaging and shipping samples on dry ice to a central lab, completion of GCP visit documentation and laboratory requisition forms.

The outcome

During the trial, Accellacare was able to perform visit activities for patients at alternate sites to reduce potential drop-out. For example one patient was on vacation and another patient was able to have some visits in a state where they attended school and other visits in their home state.

By making study participation more convenient for patients, the site was able to achieve its enrolment goal of 32 patients from a 15 state geography. As a result, the study drug went on to receive Orphan Drug status from the FDA.



Geographically dispersed patient recruitment from a single site

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