

Implementing Short Start-Up Timelines with No Study Disruptions

1 Year

(Remainder of Study)

Duration

60+

Patients Projected

10

Potential Visits
Per Patient

U.S.

Country

A global medical research and drug company focusing on rare diseases engaged with a home trial services vendor to support an endocrinology study. After a series of challenges threatened the study's success, the Sponsor turned to Firma to handle the home trial visit assessments with minimal impact on the sites, patients and timelines.

The Sponsor's phase II endocrinology study evaluated the safety and efficacy of hormone replacement therapy in patients with primary hypothyroidism, a condition in which the thyroid gland fails to produce an adequate supply of thyroid hormones. The study involved home trial visit assessments for all 60 participants across 25 sites in the U.S. Each visit included biological sample collection, processing and shipping to a central laboratory. While the home visits were short and straightforward, they were integral for monitoring the safety of study participants.

Study Challenges & Firma Solutions

The Sponsor experienced several challenges while working with the initial home trial services vendor. When the problems became insurmountable, the Sponsor sought help from a more experienced vendor to turn the study around within an expedited timeframe. With a proven success record, of over 9 years in the home trial service industry, Firma stepped up to the challenge.

#1

VENDOR TRANSITION

The vendor transition happened over the end-of-year period when staffing resources typically have planned holidays. **Firma promptly identified and assigned staff and collaborated daily with the Sponsor and various vendors to successfully transition all activities.**

#2

SHORT TIMELINE

A typical start-up timeline takes 6-8 weeks, but due to the nature of this study, the timeline was compressed to 3 weeks. **To streamline the process without compromising quality, Firma increased the start-up team, reviewed all client documents as soon as the work order was executed and partnered with the sponsor to expedite reviews of Firma study-specific material and decision-making.**

#3

LIMITED TIME TO PROCURE EQUIPMENT

Due to the short timeline, Firma had limited time to procure equipment for the study. Typically, there would be a lead time of 6-8 weeks to get the necessary equipment. But in this case, the home health services providers needed the equipment as soon as possible. **Firma leveraged the existing inventory in its warehouse to supply the providers with equipment and prevent any delays to the home visits.**

Results

Despite a fast vendor transition, short timeline and limited time to procure equipment, Firma met expedited start-up timelines with a rescue study that ensured each of the 60 participants had the opportunity to receive home visits with no disruptions.

