VIRTUAL

Navigating Time-Sensitive Sample Collections During a 100% Decentralized Clinical Trial

TYPE

Decentralized Clinical Trial

DURATION

5 Months

PATIENTS SUPPORTED

48

COUNTRY

U.S.

When COVID-19 forced a shelter in place for much of the world, the demand for in-home clinical trial solutions skyrocketed, pushing pharmaceutical companies to adopt new decentralized strategies to ensure no risk to the clinical study and intended data capture. To address increasingly urgent and changing needs, a top 20 global pharma company partnered with Firma to design and execute a 100% decentralized clinical trial with a protocol that typically requires in-person site visits.

The company sought to conduct an immunology study on Primary Immune Deficiency Diseases (PIDDs), rare genetic disorders that impair the immune system. Without a functional immune response, people with PIDDs may be subject to chronic, debilitating infections.

The trial would be completely decentralized and include mandatory home trial visits per protocol. The sponsor had concerns as the human peripheral blood mononuclear cells (PBMCs) samples would be viable only 24-48 hours after collection, so time was of the essence. The study also involved patients as young as 2 years of age, which has been historically challenging for the industry as pediatric clinical trials see a higher rate of study withdrawals.

Firma planned and executed home trial visits with the patients, which included biological sample collection and processing and shipping to a central laboratory. The complexity of accurately collecting and processing the biological samples was crucial to the study's success.

VIRTUAL

Study Challenges & Firma Solutions

1

HOME TRIAL PROVIDER IDENTIFICATION

Unlike with traditional brick-and-mortar sites, fully decentralized trials have the added challenge of a potential vast geographic spread. Communication with the recruiting site was critical. Firma established a collaborative network of communication between site, sponsor and required vendors. With this critical level of communication and planning in place, everyone was prepared to set up and conduct all home trial visit activities successfully. The Firma team knew they needed to source providers within the timeframe, with no advance information regarding participant location. Firma's robust network of home trial providers, spanning the entire U.S., was able to rise to the challenge and meet the needs of all 48 participants, across 30 states.

2

HOME TRIAL PROVIDER TRAINING

Thorough and precise training was critical to ensure the accuracy of sample collection and processing. Through communication with the central laboratory, Firma was able to gain additional information to create improved sample processing instructions for the home trial providers, learning the results were more accurate when the sample was inverted 8-10 times post-collection. Firma was also mindful of the Sponsor's cost and, where possible, ensured the same provider was able to provision care for multiple participants, overall reducing training costs for the Sponsor.

3

IMMUNOCOMPROMISED PATIENTS

The study involved immunocompromised patients, who are at risk for severe and prolonged illness. This was especially challenging as the trial occurred during the onset of the COVID-19 pandemic when vaccine status of providers was uncertain. Firma worked to meet the patient's preferences for provider vaccination status by coordinating an additional level of provider screening — implementing vaccination status matchmaking — within the timeline and with no impact on the budget.

4

PBMC SAMPLE VIABILITY

The study protocol required one-time sampling of PBMC samples for each patient. PBMC samples are used to determine the overall wellness of a patient's immune system. In this trial the samples were critical. PBMC samples also have a very short viability window in which they must be processed at the central laboratory post-collection. Firma understood the importance of every sample arriving on time, only 24-36 hours post-visit; after that, accurate results would not be feasible to obtain. Clear expectations were set with couriers and the central laboratory. Visit time constraints were established to ensure no samples were collected after 2 p.m. or on Fridays, ensuring couriers would meet the open hours of receiving at the central laboratory. The Firma team ensured to relay this critical timeframe to each provider during training and ensured that Firma stayed highly involved with every provider to ensure sample processing went smoothly. As a result, all samples were delivered to the central laboratory on time.

5

DOCUMENT RETAINMENT

With the rapidly evolving environment of clinical trials during the height of the COVID pandemic, the Firma team needed to quickly adapt to the fully decentralized site model. There was no physical site to retain any visit documentation. Firma worked to secure a compliant method of document retention and rapidly adapted the process of certified electronic copies for all study source and regulatory documentation.

VIRTUAL

Results

Firma's robust oversight and involvement with our providers post-training ensured visit timeframes were adhered to and laboratory sample collection and processing met expectations. Firma's providers were aware they could contact the Firma team for assistance at any time during the visits.

Of the 72 electronically consented participants, 48 participants passed screening, inclusive of children as young as 2 years of age. Every participant engaged in a home trial visit, and over 50 providers were provisioned to ensure the demand was met.

Not only did Firma overcome various potential challenges to ensure study completion, but the Firma team was able to meet the endpoints for the required data within 5 months, an overall reduction in the originally contracted timeline, of one year, of greater than 50%.

Every visit was successful, with 100% participation — no missed sample collections.

> *The Sponsor was highly impressed and satisfied with Firma's services and success in being able to complete the visit within the timelines suggested.*
>
> **- Firma Project Manager**