RESCUE

Patient-Centric Approach Helps Global Study Exceed Goals for Recruitment, Retention & Transparency

DURATION:

160 Weeks
(Main Trial)

104 Weeks
(Open Label Extension)

PATIENTS SUPPORTED:

74
(Main Trial)

45
(Open Label Extension)

VISIT FREQUENCY:

Weekly

COUNTRIES:

- Canada
- New Zealand
- Australia
- Poland
- Denmark
- US

A mid-sized pharmaceutical company contracted with several home health providers (including Firma) for patient support. After experiencing delivery issues with one home health provider, and based on Firma's exceptional and consistent operational performance, the Sponsor asked Firma to assume additional global responsibilities and increase the patient-centric approach of the trial.

STUDY CHALLENGES AND FIRMA RESOLUTION

While a fairly straightforward protocol, the volume of visits, the remote location of some patients, and the 11-hour shelf-life of the medication proved problematic for the other home health organizations originally contracted. Firma assumed expanded responsibilities from the other home health providers to enhance patient support.

1 VOLUME OF VISITS

Administering weekly infusions for patients was clearly a burden home health visits would help relieve, but with such a large number of patients involved, this still equated to a significant number of visits. The frequency of monthly visits was too challenging for another provider to maintain, and they were suffering from unassigned and uncompleted visits. Firma team members were brought in for patient support and have successfully met this volume of trial visits. **In the month of April 2019 alone, for example, Firma effectively supported approximately 350 visits on this project.**

2 REMOTE PATIENTS

Patients located away from the clinical site may present a challenge in the "traditional" clinical trial model. However, a home health visit approach excels in this environment when performed correctly. For this study, **Firma has supported patients more than 12 hours from their investigative sites and in very remote locations** (so remote, in some instances, that commercial shipping companies are unable to guarantee overnight shipments). This structure has enabled patients to participate in this trial who, under traditional trial approaches, would forgo the potential for trial involvement.

FIRMA
CLINICAL RESEARCH

3 DRUG STABILITY

Once reconstituted, the shelf-life of this particular drug is only 11 hours and cannot be couriered via flight. Firma worked diligently to secure pharmacies that were convenient to the patient location or could mix and ship the IP direct to the nurses in advance of each home health visit. Meeting these critical needs ensured proper IP reconstitution and administration in adherence with the protocol.

RESULTS

Despite the challenges, Firma was able to identify both a primary and a backup nurse for each area, establish KPIs to measure and communicate ongoing performance, and deliver regular status reports meeting the transparency needs the sites and Sponsor were requesting.

As a result, the Sponsor was able to improve the management of patient enrollment and safety parameters, resulting in better site and patient engagement and operational efficiency.

Firma also reduced site burden, facilitating patient recruitment, retention, and study management. With Firma as a trusted partner, the Sponsor has been able to engage sites and patients who otherwise might not be able to participate.

Based on strong performance, transparency, and operational results, the Sponsor has asked Firma to expand oversight to additional countries in support of this global study.

> “The Sponsor has been especially impressed with our management style and level of transparency. It’s not always easy, but open communication is a critical part of making home health visits work. When there’s an issue—and issues are to be expected when you’re working with complex clinical trials—we come to them early and with solutions in hand.”
>
> **- FIRMA PROJECT MANAGER**