

## CASE STUDY:

### UTILIZING A MOBILE NURSING SOLUTION TO HELP ENHANCE PATIENT RECRUITMENT AND RETENTION IN A PEDIATRIC CLINICAL TRIAL INVOLVING IV INFUSIONS

#### Background

A biotech company conducting a phase 3 clinical trial for a promising new treatment for a rare disease, faced significant challenges in recruiting and retaining pediatric patients. The trial required weekly intravenous (IV) infusions, with visits lasting up to six hours, creating a substantial burden for families, many of whom lived far from the study sites.

To address these challenges, the Sponsor sought a vendor with proven expertise in delivering mobile nursing solutions for clinical trials. The Sponsor recognized that enabling patients to receive treatment in their own home would significantly enhance trial participation by reducing logistical and financial burdens on families. Equally important was ensuring the chosen vendor could maintain that same level of consistency, quality of care, and clinical rigor as the traditional trial sites.

#### WEP's Solution

The Sponsor partnered with WEP to leverage our mobile nursing solution, which is tailored to enhance clinical excellence and provide the highest level of care to patients. The key components of this solution are outlined below:

## Nurse Training:

The core of any trial lies in the care provided by our skilled mobile nurses. Each nurse is carefully selected based on their expertise and experience and is trained to meet rigorous standards, including ICH-GCP and National Data Protection requirements. Nurses undergo comprehensive training on protocols that include a thorough review of relevant policies and procedures, ensuring adherence to both local and global regulations and guidelines.

For this trial, the nurses were trained on:

- Complex IV infusion procedures
- Pharmacovigilance (e.g., adverse event reporting)
- Data collection and remote monitoring
- Good Clinical Practice (GCP) compliance

## Scheduling:

Ensuring that each patient is visited by the same dedicated nurse for every home visit is a top priority. This continuity fosters trust, enhances patient comfort, and supports consistent, high-quality care – especially for pediatric patients. Our nurses are carefully recruited and assigned to specific patients by our project and clinical teams, utilizing electronic scheduling tools to optimize assignments based on patient location and treatment schedules.

We recognize that every family has a unique schedule, and our goal is to integrate treatment seamlessly into their daily lives. To achieve this, we offer flexible scheduling options, including early visit times or adjustments to accommodate their routines. This flexibility is carefully balanced with a strict adherence to study protocols, ensuring both convenience and compliance.

Leading up to each visit, families and caregivers receive reminders and confirmations via a mobile app or phone calls, reducing the risk of missed appointments.

## Home Infusion Process:

A home healthcare assessment is conducted prior to the visit to ensure the patient's home setting is suitable for IV administration. Additionally, parents and caregivers receive thorough training on home infusion procedures and safety protocols, so they are aware of what to expect on the day.

Our nurses arrive at the patient's home with all the equipment required to carry out the home visit. This includes:

- Pre-prepared medication
- Infusion equipment (pumps, specialist giving sets and filters, IV bags, etc.)
- PPE and emergency response kits in case of adverse reactions

Our nurses follow strict infection control protocols and use sterile infusion setups. IV infusions are administered via infusion pumps, per protocol-specific timing and dosing requirements. Vital signs and patient well-being are monitored before, during, and after treatment.

A telemedicine support system allows real-time communication with principal investigators (PIs) for immediate medical oversight. Nurses log all infusion details, AE reports, and patient responses in electronic case report forms (eCRF).

## Use of Child-Friendly Strategies:

Our mobile nurses are trained to use various child-friendly strategies during home visits to ensure a positive experience for pediatric patients. This is particularly important for this trial, as the visits can last several hours. The strategies used, some of which are outlined below, help ease anxiety, build trust, and improve cooperation.

- **Creating a Friendly Atmosphere:**

Our nurses start with a warm smile and introduce themselves in a way a child can understand. They explain procedures in simple terms, using age-appropriate language to describe what they are going to do.

They also are careful to avoid words that are likely to scare the child, like "shot" or "pain", where possible. The nurses also involve the parents and caregivers, encouraging them to stay close to offer reassurance.

- **Using Play and Distraction Techniques**

Nurses bring small toys to the home and let children hold stuffed animals during procedures. They also make use of storytelling and songs to help distract the patients and keep them calm. Simple games, like counting or "I Spy," can also help make procedures less intimidating.

- **Providing Choices and Patient Involvement**

Allowing the patients to make small choices and giving them options like "Do you want me to check your arm or your leg first?" offers them a sense of control. Additionally, asking if they'd like to involve familiar toys, technology, or family pets helps them relax further.

- **Managing Anxiety and Fear**

Teaching simple deep breathing techniques helps soothe patients. Offering praise and encouragement boosts their confidence, while small rewards like sweets or stickers give them something positive to look forward to at the end of the visit.

## **Expert Logistics Coordination:**

The complex trial protocols demand precise planning to ensure the Investigational Medicinal Product (IMP) is delivered on time and administered safely, consistently, and in compliance with trial protocols.

The logistics behind delivering the IMP to patients is coordinated by the Project Management (PM) team to ensure timely treatment delivery. The team works closely with trusted partners to manage every step of the process – from coordinating the collection of IMPs from the pharmacy a day before treatment, to ensuring that the treatments arrive within the crucial 24-hour window required for each patient.

To meet the unique needs of pediatric patients, deliveries are scheduled early in the morning, allowing children to attend school post-treatment without disruption.

Real-time tracking technology further enhances this process to monitor progress and address any potential issues.

If a delay occurs, adjustments are made for new delivery routes or to reschedule. This makes sure established protocols are followed and minimizes any inconvenience for the family so that the patient's treatment remains on track.

## Conclusion

The success of this pediatric trial is largely attributed to our team's expertise in managing the complexities of IV infusions and ensuring flawless logistics coordination. By seamlessly integrating expert clinical nurses with a highly skilled operational team, WEP delivers timely treatments while prioritizing patient safety. This patient-centric approach not only addresses the needs of families but also fosters trust and reliability throughout the study. As a result, the Sponsor has expressed high satisfaction with WEP's meticulous logistical coordination and commitment to providing the highest level of care to both patients and families.