

CASE STUDY:

HOW WEP'S COUNTRY COORDINATOR TEAM HELPS SUCCESSFULLY DELIVER AN ONGOING MOBILE NURSING SOLUTION FOR A GLOBAL RARE DISEASE TRIAL

Background

A biopharmaceutical company (Sponsor) launched a global clinical trial to evaluate a promising investigational therapy for a rare and rapidly progressive neurodegenerative disease. Given the severe mobility impairments experienced by patients and the need for frequent monitoring, the Sponsor decided to incorporate home nursing visits into the protocol to minimize travel burdens and maximize patient retention.

Challenge

Patients in this trial are located in 20 countries, across 4 different continents, meaning the Sponsor has to accommodate varying local regulations, languages, and healthcare infrastructures.

Visits require:

- Trained homecare nurses to conduct clinical assessments, collect samples, and document findings
- Strict adherence to visit windows
- Accurate handling and timely shipment of temperature-sensitive biological samples
- Thorough documentation that meets GCP and GDP standards
- Close collaboration with nurses, clinical sites, vendors, and Sponsor teams

A single missed shipment, scheduling error, or documentation discrepancy could compromise data integrity or require a repeat visit – neither of which are acceptable, given the disease’s rapid progression.

WEP Solution

To meet these challenges, the Sponsor partnered with WEP to utilize our global and comprehensive Mobile Nursing Solution – a service built to combine clinical rigor with flexibility, ensuring high-quality, hands-on care, while maintaining consistency across multiple regions.

A key component of WEP’s mobile nursing delivery model is our Country Coordinator Team. As part of our model, a Country Coordinator is present at every home visit, via video-call, to provide readily available and consistent support for our treating nurses, throughout the entire clinical study. They work hand-in-hand with the WEP PM, mobile nursing staff, investigator sites, logistics and courier partners, and the Sponsor team to ensure that every aspect of patient participation is as seamless and as comfortable as possible. They help manage logistics, anticipate and mitigate challenges, and enable the flexibility and precision this kind of trial demands.

For this study, WEP has assigned a Country Coordinator for each country in scope. Below, we take a closer look at the key elements of their role.

Activities Carried out Prior to the Visit

Prior to a home visit, our Country Coordinators carry out a series of tasks to help prepare all study stakeholders and ensure everything is in the right place at the right time when the nurses arrives at the patients’ homes.

Preparing the Nurses:

- We believe that a well-prepared nurse is a confident nurse. As such, our Country Coordinators ensure that all mobile nursing professionals are certified and trained on the latest tools and protocol.

- For this study, training includes:
 - Good Documentation Practices (GDP)
 - Source documentation standards
 - Country-specific regulations that must be followed
 - Assessments specific to the protocol
 - Equipment use (such as ECG devices)
 - Platforms for specimen tracking.
- This training ensures the nurses are adequately prepared to deliver standardized care, regardless of country or healthcare system, and allows the Sponsor to maintain trial integrity across different regions.

Coordinating Schedules:

- Each visit to a patient's home requires the seamless coordination of the patient, investigator site, mobile research nurse, and logistics partners – a process which is fully managed by our Country Coordinators.
- They align the availability of all study stakeholders and manage visits so that the nurses can carry out all study activities within the required shipment and delivery windows, set-up with our transportation providers. They also ensure that each visit schedule allows enough time for clinical assessments, sample handling, and courier arrival. This process involves addressing real-time issues, such as a sick nurse, a late courier arrival, or a rescheduled visit.
- Our Country Coordinators' attention to detail and responsiveness prevent delays and help maintain both compliance and patient satisfaction.

Managing Logistics:

- Country Coordinators organize the shipment of all visit essentials, to ensure everything arrives with the nurse on time and in working order. Since logistics can be unpredictable, they prepare contingencies to safeguard against transit issues. They are also responsible for scheduling courier pick up times for samples to be collected at the end of the visit and transported to the lab.

- For this study, our Country Coordinators organize for the couriers to arrive 30 minutes prior to the visit's expected end time. They provide the couriers the mobile nurse's telephone number, so they can update the nurse if they are going to be late, and the nurse can then delay drawing blood samples.

Activities Carried out During the Visit

During a home visit, our Country Coordinators are responsible for ensuring that the treating nurses are fully supported and that all study procedures are completed accurately, promptly, and in compliance with regulatory and protocol standards.

Supporting WEP Nurses:

- Our Country Coordinators attend every home visit via video conference. This attendance ensures our nurses have support throughout the entire home visit. For example, if equipment or supplies are missing, the Country Coordinators carry out corrective action so that the visit can continue successfully.
- When the nurses need to liaise or work with logistics teams during the visit, the Country Coordinators oversee these interactions and ensure they run smoothly.

Providing Real-Time Quality:

- As the WEP nurses carry out the appropriate study procedures, our Country Coordinators provide real-time quality checks to enhance accuracy and streamline documentation. They oversee key tasks to ensure the following:
 - Source documentation is completed and in compliance with GCP and GDP
 - Assessments are completed at the correct time and in the correct order
 - Lab samples are handled appropriately and in the required temperature-controlled range
 - There is consistency between app entries (TruLab App for live sample management) and paper documentation (Lab Requisition Forms and the Source document)

Upholding Sample Integrity:

- One of the study's most stringent requirements involves biological sample handling, specifically blood samples that need to be placed on dry ice within 60 minutes of being drawn. Our Country Coordinators help to uphold sample integrity by verifying proper collection, labeling, and shipment conditions.

Activities Carried out After the Visit

Once a home visit is completed, our Country Coordinators carry out a series of follow-up activities to help ensure the study continues to run smoothly and the Sponsor is kept up-to-date and informed.

Manage Logistics:

- Our Country Coordinators manage the collection of any reusable equipment, such as ECG monitors, that the nurses will not take away with them. They ensure the equipment is retrieved, sanitized, and prepared for reuse or redeployment.
- They also ensure that all scanned copies of source documents are sent to the site within 48 hours of visit completion and arrange for the originals to be shipped to the site.
- They track specimen deliveries to ensure samples reach the central lab with within the defined time window. This involves troubleshooting any sample shipment issues that may arise, such as delays or temperature excursions.

Keep all Stakeholders Informed and Up to Date:

- Finally, Country Coordinators maintain regular contact with all study stakeholders. Each Country Coordinator has weekly catch-up calls with the WEP PM and investigator sites and monthly catch-up calls with the Sponsor team.

- This allows our Country Coordinators to provide regular status updates, resolve patient or nurse questions, and maintain stakeholder alignment.

Conclusion

The success of this ongoing global mobile nursing program hinges on many complex operational functions that must be orchestrated efficiently to ensure we deliver the best care to patients in the study. Our Country Coordinators make this possible. Their diligence, flexibility, and proactive management ensures protocol integrity and consistent patient care – despite the challenges of fragile participants and tightly sequenced procedures.

Including the Country Coordinator Team as an integral part of our delivery model allows WEP to deliver a high-touch, patient-centric experience, without compromising compliance or clinical integrity. The Sponsor recognizes this operational excellence as essential to the trial's ongoing success and the well-being of its participants.