CASE STUDY

Seamless mobile clinical services increase patient recruitment and retention in rare pediatric disease trials

A KEY QUESTION

How can sponsors integrate a patient-centric model, directly connecting clinical trials with pediatric patients and making trial participation easier?

KEYWORDS Rare Disease, Pediatric Population, Recruitment, Adherence, Retention, In-Home Specimen Collection, Site Support

Recruiting patients can be particularly challenging in rare pediatric disease clinical trials, highlighting the need to create an optimal patient experience and enhance study retention.

This case study highlights how two different sponsors, a mid-sized, U.S.-based biopharmaceutical company and a large, global biopharmaceutical company, both chose Fortrea's Mobile Clinical Services (MCS) to:

- Support recruitment and retention
- Reduce patient and site burden
- Perform difficult procedures for geographically dispersed participants

Learn how Fortrea has developed tailored approaches, seamlessly managed logistics and maintained study integrity while ensuring patients receive continuous medical care in their homes.

Meeting sites' and patients' needs with Mobile Clinical Services

In a Phase I-III gene transfer clinical trial and Phase III gene therapy treatment clinical trial, Fortrea provided:

- Specimen collection (blood and urine), body weight measurement, concomitant medications and signs and symptoms
- Logistical support to manage specimen shipment
- Patient-centric solutions designed around the needs of the pediatric population

As a result of these tailored services, both the sponsor and patients realized several benefits, such as:

- More cost-effective study visits compared to those performed at the site
- Increased participant comfort and study adherence
- Reduced patient and site burden

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Understanding the challenges faced in pediatric trials

In these trials, one involving a rare genetic disorder and the other studying a rare metabolic disorder, Fortrea needed to address several key factors. These included:

1. **Reaching patients in remote locations**
   Rare disease trials frequently encounter shortages of participants, a situation that is further exacerbated in pediatric patient populations. To increase participation, both studies typically accept participants who live in remote areas. These studies included patients from rural locations that lacked public transportation, as well as those who lived over 1,200 miles from the nearest study site.
2. **Obtaining sufficient sample volumes**
   The study participants have small, easily collapsible veins, which often leads to insufficient blood samples and requires re-test visits.
3. **Gaining patient trust**
   Pediatric patients often experience anxiety during blood collections and need to feel comfortable for the procedure.
4. **Supporting site staff**
   Clinical site staff can experience burnout due to the effort, resources and time required to run the trial and manage the logistics.
5. **Reducing sponsors' costs**
   The sponsors face significant costs in transporting participants and their caregivers to study sites, especially when travelling from remote areas.

Developing tailored approaches with Mobile Clinical Services

To overcome the challenges associated with these studies, the sponsors asked Fortrea's Mobile Clinical Services to work with specific patients. Fortrea then deployed several tailored approaches with its Mobile Clinical Services, such as:

- **Scheduling consistent health providers to reduce patient anxiety:** Fortrea assigned highly experienced mobile clinicians to engage in play with the participants before starting the blood draw procedure. Then, the same nurse would attend all subsequent visits to maintain familiarity and comfort. For particularly nervous individuals, two mobile clinicians would visit: one to distract the participant while the other performed the venipuncture, ultimately helping participants feel more comfortable during the blood draw
- **Managing complex visit logistics:** Fortrea ensured that each visit had the necessary kits, arranged for courier services to transport biological samples to the central laboratory and supplied qualified nursing personnel
- **Keeping sites informed with proactive communication:** All visit outcomes were meticulously recorded in the source documentation and promptly shared with the site to keep site staff fully informed. Any abnormalities were communicated to the site immediately via phone and email to facilitate any necessary follow-up or monitoring
- **Facilitating rapid collections:** The studies often had urgent, ad-hoc needs for blood collections to monitor the participants' results and achieve critical milestones. Fortrea's Mobile Clinical Services quickly facilitated these collections, ensuring patients received continuous medical care right in their homes

Evaluating the results

As a result of the Mobile Clinical Services team, patients felt more at ease and comfortable with the venipuncture procedure in their familiar home environment. This patient-centric procedure also impacted recruitment and retention rates. As compared to participants who went through "traditional" collection methods at the site, the participants using Mobile Clinical Services had:

66%
more patients randomized

7%
higher retention rates

In the other rare disease study, Fortrea has conducted more than 200 visits across four studies within the program, spanning 12 countries over a nine-year collaboration with the sponsor. The sponsor recently submitted a Biologics License Application (BLA) to the FDA and initiated a Long-Term Follow-Up (LTFU) study. Again, they requested Fortrea's Mobile Clinical Services for this study, further demonstrating their continued trust in the team and Fortrea's commitment to supporting unique patient populations.

Learn how Fortrea's Mobile Clinical Services delivers patient-focused solutions to help improve recruitment and retention in rare disease studies:

fortrea.com/clinical-solutions/clinical-development/mobile-clinical-services

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