CASE STUDY

# Supporting patient retention in a rare disease program with Fortrea Mobile Clinical Services

As clinical trial models continue to evolve, we are examining ways to improve service delivery through decentralized clinical trial (DCT) solutions and serve as more than a partner for our clients. This case study highlights the role of Fortrea Mobile Clinical Services to decrease the burden of study participation and increase patient retention in a rare disease program.

## Understanding the need to increase patient centricity

In a rare genetic disease program, six studies spanning Phase I-III aimed to enroll more than 140 patients across 14 countries. The investigational product was to be given to study participants every two weeks as an IV infusion treatment, a procedure that required up to three hours to complete.

With this treatment schedule, the sponsor recognized that it may be difficult to maintain patient retention in the studies. The potential travel burden also presented a challenge to reach patients in rural or remote areas away from the investigator site.

The sponsor was already working with another CRO but turned to Fortrea to help proactively address these hurdles. Together, they created a partnership between the study team, the CRO and Fortrea Mobile Clinical Services.

## KEY TAKEAWAYS

**How Fortrea brought the rare disease studies closer to the patients:**

- Engaged and managed two central pharmacies to support 13 countries
- Coordinated specialty cold-chain couriers to ensure stability of investigational product
- Oversaw vendor management to ensure protocol compliance with the sponsor and the CRO
- Provided supply chain forecasting to mitigate potential courier disruptions
- Performed in-home infusion services for patients to support investigator sites and increase patient retention

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## Developing a solution to minimize the patient burden

Charged with supporting in-home study visits to provide IV infusion treatments, Fortrea first engaged two central pharmacies—one in the U.S., and one in the EU—and provided training to the staff to ensure protocol compliance with the handling and reconstitution of the investigational product.

Next, the team brought on specialty couriers that offered cold-chain shipments with temperature-monitoring services during transport and distribution. They needed to ensure that the investigational product, which had limited stability of 24-36 hours post-reconstitution, would not experience adverse temperature deviations. To mitigate potential courier disruptions and unforeseen events, the team also performed supply-chain forecasting and management.

In each of the 14 countries, Fortrea trained country coordinators to manage vendors and monitor overall compliance to the protocol. They also trained the central pharmacies and investigator sites on storing, dispensing, distributing and destructing the investigational product.

## Evaluating the results of the partnership

Over the last five years, more than 5,200 study visits have been conducted, 43% of which have been supported by Fortrea Mobile Clinical Services. In addition, the central pharmacy serviced 108 of the 140 enrolled patients, highlighting the key role the team played in supporting patients.

Throughout these studies, a close collaboration between Fortrea Mobile Clinical Services and the country coordinators helped ensure appropriate vendor management and protocol compliance at both the investigator sites and the central pharmacies.

Looking ahead, current study participants have the option to participate in an open-label extension program, which will increase their treatment duration for an additional 4+ years. Fortrea Mobile Clinical Services will continue to serve as an integral part of the overall success of the program by supporting patient-centric practices in these extension studies, minimizing travel burden for patients and ultimately increasing patient satisfaction.

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