

CASE STUDY

Innovative approaches help recruit and retain patients in a rare disease hematology study



A sponsor contracted Fortrea to run its Phase III hematology study and enroll 250+ rare disease patients in a highly competitive therapeutic area. Learn how Fortrea implemented collaborative strategies to address recruiting challenges, maximize retention and reduce patient burden with digital health innovation.

Taking action to deliver a complex study

With a five-year multi-national rare disease study spanning the Americas, EU and Asia Pacific, Fortrea needed to think creatively about how to meet expectations for the sponsor, sites and patients.

Leveraging sites to support recruitment:

Fortrea tapped into its network of trial sites to help increase awareness, improve visibility and credibility and strengthen recruitment.

Creatively designing the study:

With a lengthy study timeline, Fortrea wanted to ensure that patients would remain engaged. Working with the sponsor and sites, they designed a decentralized approach with telehealth and home nursing visits to collect study data and maintain patient connections.

Reducing patient burden:

Beyond remote study visits, Fortrea also used electronic patient-reported outcomes (ePROs) or eDiaries to support remote data collection. Digital health technology was essential as the sponsor had requested more than 10 clinical outcome assessments (COAs), and this amount had the potential to impact the patient burden.

Protecting study endpoints:

In concert with remote data collection, patient compliance with ePRO was tracked to maintain data quality and protect the study's endpoints.

Achieving success through thoughtful collaboration

Fortrea demonstrated its expertise in navigating challenges, ensuring compliance with regulatory standards and enabling high-quality data collection. Key achievements included:

- **Delivered an on-time startup:** Fortrea's Digital Health Project Management team played a large role in licensing the numerous ePRO test instruments to enable startup
- **Exceeded recruitment timeline:** Recruitment was completed 52 days ahead of schedule
- **Surpassed retention goals:** ~85% retention was achieved, beating the expected retention rate of 80%
- **Protected study endpoints:** The use of eDiaries protected study endpoints and enabled proactive intervention of potential issues, as none of the participants dropped out due to IP discontinuation
- **Reached a high compliance rate:** Fortrea reached ~94.8% questionnaire compliance for the primary endpoint

With the combined experience of its rare disease leaders, digital health strategies and close connections between the sponsor, sites and patients, Fortrea successfully delivered this complex, rare disease study.

Learn how Fortrea's multidisciplinary experts apply their insights and experience to advance your [rare disease drug development program](#).

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