CASE STUDY

Driving patient recruitment and retention in a complex pain clinical trial

A KEY QUESTION

What strategies enable the recruitment of quality, compliant participants for a complex trial to support quality endpoint data collection?

KEYWORDS Pain Clinical Trial, Patient Recruitment

When every patient matters, how do you find the right ones and confirm long-term engagement with the study? In a challenging Phase IIb pain trial, Fortrea faced the ultimate patient recruitment and retention puzzle: high potential for non-compliant participants, subjective pain reporting, high screen failure potential, and a placebo-controlled design. Through strategic patient validation, targeted education initiatives, and rigorous site management, we transformed these challenges into remarkable success—achieving full enrollment within the targeted 12-month timeline while securing an exceptional 93% patient retention rate. Here's how we turned potential roadblocks into pathways for clinical advancement.

Addressing recruitment and data integrity challenges

This Phase IIb pain trial presented a range of recruitment and patient compliance hurdles, from the inherent subjectivity of pain assessment, to the risks associated with a placebo-controlled design. Fortrea needed to implement solutions that would drive quality enrollment and retention:

- **Pain assessment and patient education:** The subjective nature of pain and the difficulty of differentiating neuropathic pain from other pain forms required enhanced site training and patient education
- **Duplicate and "professional" patients:** Given the importance of patient-reported outcomes in pain clinical trials, enrollment of duplicate patients posed a significant risk to data integrity
- **Potential of placebo-controlled design to limit interest:** Placebo-controlled pain trials face reduced enrollment interest due to a lower perceived treatment benefit and potential placebo effect reducing detection of therapeutic response
- **High screen failure rates:** With a historical 60% screen failure rate, Fortrea needed to proactively address site morale to ensure staff did not become disengaged
- **Need for timely recruitment:** To meet the sponsor's development goals, enrollment needed to be completed within 12 months

Fortrea

Solutions to boost enrollment and retention

Validation provider: In pain studies, where subjective reporting is already challenging, compromised data isn't just a risk—It's a significant threat to trial validity. Fortrea implemented rigorous biometric validation at screening through our specialized provider, identifying and filtering out duplicate and professional participants before they could impact the study. This proactive approach flagged **7.5% of potential enrollees** as protocol violations—participants who would have otherwise diluted the statistical power of our results and potentially misled crucial development decisions.

Supportive patient education: Through our experienced patient engagement team, we created tailored patient education focusing on the unique challenges of neuropathic pain reporting. Our comprehensive training program equipped both sites and patients, with the tools to properly report neuropathic pain and the necessity of objective reporting—a critical distinction for participants with diabetes. This wasn't just about providing information; it was about building confidence in pain assessment, setting clear expectations about permitted pain relief options, and fostering commitment to the study schedule. By investing in this education upfront, we built a foundation for the remarkable **93% retention rate** that followed.

Results: Outstanding retention and strategic patient selection

By completing enrollment in less than 12 months, Fortrea successfully met the sponsor's timeline.

The trial's 93% retention rate was exceptional given the typical challenges of placebo-controlled pain studies in this therapeutic area. This result reflects the value of engaging the right patients, equipping sites through targeted training, and supporting participants.

Patient validation efforts led to a **pre-identified 7.5% of patients as violations** through Fortrea's screening vendor. Although this was higher than the projected benchmark, the screen failure rate reflects a focus on protocol integrity and indicates success in preventing skewed data.

Partnering for confident, high-integrity trials

With deep experience in complex therapeutic areas and a commitment to data integrity, Fortrea brings tailored solutions that support smarter enrollment and sustained engagement. Our proactive approach to patient selection and site support helps sponsors run more efficient, compliant trials.

See how we can support your **neuroscience study**.

For more information on how Fortrea can support your complex clinical trial, **contact our team today.**

Fortrea