CASE STUDY

Overcoming challenges in a complex Phase IIb pain clinical trial

A KEY QUESTION

How can a CRO accelerate recruitment and improve retention in pain studies with complex measurement challenges?

KEYWORDS Pain Clinical Trial, Patient Retention

When a pharmaceutical company needed to conduct a complex Phase IIb trial in pain, they faced several critical challenges that could potentially derail their timeline and compromise data integrity. The 100-site, 500-patient study required specialized experience with multiple clinical outcome assessments (COAs) and navigating the inherent complexities of pain measurement. Drawing from our deep experience in pain studies, Fortrea implemented a comprehensive strategy that addressed each challenge head-on.

Addressing nuances of the patient population

Pain trials must address the subjectivity of pain reporting, the complexity of identifying the right patients, and proper endpoints measurement to provide high data quality and minimize dropout rates.

CHALLENGE: Duplicate or "professional" patient enrollment.

ACTION:
Enhanced patient screening through Fortrea's vendor partner.

LESSON LEARNED:
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.

CHALLENGE: Complexity of pain reporting and placebo mitigation.

ACTION:
Mandatory training for sites and patients on identifying/reporting symptoms and placebo mitigation strategies, with retraining as needed.

LESSON LEARNED:
Training is key in protecting the study endpoint making sure participants are adequately and truthfully reporting their pain.

Establishing a strong and clear message about consistency in placebo response mitigation and maintaining it throughout the full study duration is critical.

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Collaborating with sites and investigators

Due to the complex nature of this pain clinical trial, specialized experience was necessary. Selection of the right sites through Fortrea's experienced site partnership team, and close collaboration with senior leadership involvement across departments, enabled rapid site activation.

CHALLENGE: Prolonged site identification due to COA experience requirements.

ACTION:
Use of operational knowledge from previous Phase II studies to streamline feasibility survey to focus on key assessments required.

LESSON LEARNED:
Work with sponsors to determine which COAs sites must have previous experience with and allow some flexibility for others.

For sites without the full COA training, comprehensive rater training and rating oversight provided data quality while allowing sponsors to work with investigators from different backgrounds.

CHALLENGE: Necessity of competitive investigator grant budgets.

ACTION:
Weekly meetings with the sponsor to review and adjust site budgets and activation timelines, with involvement from Fortrea senior leadership.

LESSON LEARNED:
Utilization of a high benchmark for investigator grants can streamline site budget negotiations.

Adapting to a complex protocol

The protocol endpoints and blinding process increased the complexity of data collection set up, and patient screening and enrollment timelines. Continued engagement and tailored solutions were essential.

CHALLENGE: Split go-live dates due to complex eCOA/EDC builds and system integrations.

ACTION:
Regularly convened critical stakeholders for fast resolutions and integration of both systems and build-up of processes with UAT reviews to prevent future changes. This involved an in-depth kick off meeting, and weekly design meetings with critical stakeholders including our DHI team, and leveraged our collaborations with data vendors.

LESSON LEARNED:
Early engagement and identification of critical stakeholders enables a smoother build and licensing process for eCOA and EDC integration.

CHALLENGE: Higher than expected screen failure rate.

ACTION:
Retraining on preventable screen failures, protocol revisions to reduce unnecessarily strict inclusion/exclusion criteria, creation of monthly modeling scenarios, and one-on-one meetings with struggling sites.

LESSON LEARNED:
Include early study feasibility discussion with investigators for practical insight on study design. Emphasize the importance of robust prescreening activities and access to full medical history.

CHALLENGE: Rapid enrollment at 50% of sites, while 30% of additional sites did not enroll any patients.

ACTION:
Centralized emails to sites with guidance on randomization timelines and active site outreach to provide enrollment and operational tips.

LESSON LEARNED:
Place importance on understanding the study patient profile, the limitations of mass recruitment campaigns for the patient population, and the value of site-owned databases.

Results

Our strategic approach delivered meaningful results that helped the sponsor meet their program objectives:

- **On-time activation:** 100 sites ready to enroll within the three month target period
- **Accelerated recruitment:** Last patient in achieved one month ahead of schedule, despite high screen failure rates
- **93% retention rate:** Exceptional patient retention due to thorough screening, education, and site training
- **Higher than anticipated screen failure rate:** This included a 7.5% violation rate pre-identified through Fortrea's screening partner; although the rate was higher than the historical benchmark, it demonstrated care in enrolling the right participants
- **On-schedule database lock:** Enabling early access to top-line data for key program decisions and investor engagement

Leverage Fortrea's extensive trial experience

Fortrea's deep experience in complex protocols for pain clinical trials, enables us to provide tailored solutions and support data quality. We consider the needs of patients, sites, and sponsors to maximize efficiency and compliance while minimizing risks.

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

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

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