

Helping clinical trial sites thrive: Lessons learned from Fortrea's Site Support and Mobile Clinical Services

A KEY QUESTION



How can tailored site support and mobile services help clinical trial sites thrive?



KEYWORDS

Clinical Trials, Site Support, Mobile Services, Operational Efficiency, Patient Engagement, Onboarding

Each site in a clinical trial has unique needs, which can vary based on the stage of the trial, the site's location and the patient population.

To help sites meet these needs and address staffing constraints, Fortrea Site Support Services offers qualified personnel to bridge gaps in clinical trial operations. In the last five years, Site Support Services has supported more than 40 clinical research studies with highly skilled professionals. In conjunction with this support, Fortrea Mobile Clinical Services has directly connected patients with clinical trials in more than 65 countries to reduce the burden on investigator sites' staff.

This case study shares a few of the challenges encountered by the teams, their actions and the lessons learned to optimize operational efficiency and boost trial performance.

Recognizing site-level challenges		Taking action
Aligning global processes with local site expectations	Fortrea and a sponsor had outlined contracted deliverables in a global operational plan but then learned that these processes conflicted with local sites' expectations in Taiwan.	Fortrea met with the sponsor and several sites in Taiwan to set clear expectations, align processes and define responsibilities. Fortrea's understanding of the cultural nuances helped strengthen relationships and enhanced site setup.
Experiencing delays in site onboarding processes	In some Asia-Pacific (APAC) countries, Fortrea learned that qualified site support staff must first be approved by the site's Principal Investigator while lengthy administrative processes at the site can further delay the onboarding process.	To avoid the risk that site staff would no longer be available due to the delay, Fortrea developed a process to keep its candidates engaged and available to start as soon as possible after site approval. Fortrea also collaborated with the sponsor to support the sites' onboarding process.
Meeting demands for data entry activities and query resolution	A site in Poland was struggling to keep up with data entry and query resolution on their own, which threatened their upcoming audit and database lock timelines.	With only three months before the audit, Fortrea identified experienced Site Support candidates who had been previously involved in sites audits. They implemented key initiatives to resolve tasks, coordinated with site staff and quickly prepared for the audit.
Facing a lack of clinical experience at a naïve site	To comply with a clinical study's expectations and meet performance metrics, a site in Spain recognized that they lacked sufficient clinical experience.	Fortrea developed site-specific processes to confirm that the naïve site complied with clinical trial standards and met enrollment expectations that aligned with other, more experienced sites participating in the study.
Supporting the continuity of care in a pediatric and adolescent study	A site in the EU was experienced in pediatric/adolescent neurology studies but needed to offer the option of both on-site and home visits to reduce the burden of study participation.	In collaboration with Fortrea Site Support Services, Fortrea Mobile Clinical Services developed an arrangement where the patient saw the same clinician at both home visits and on-site visits. Families and patients expressed satisfaction as a trusted relationship developed between the family, patient and the site.

Reflecting on lessons learned

As Fortrea Site Support Services staff have delivered more than 19,000 site support hours, they have gathered lessons learned for consistently improving operational efficiency. These include:

- **Enabling communication to promote collaboration:** Communication and transparency between all parties are essential to adapt to evolving site needs and secure alignment throughout all phases of an engagement
- **Strengthening connections between the sponsor and the sites:** Fortrea aims to coordinate with site staff and the sponsor to verify that service delivery meets the requirements of the study
- **Incorporating cultural considerations at a site level:** Recognizing cultural nuances and incorporating cultural sensitivity practices are key to developing trust, demonstrating respect and meeting the expectations of sites and patients, particularly in APAC countries
- **Understanding and owning the timeline:** A clear understanding of the timeline can help Fortrea play a crucial role in delivering timely and effective resolution of critical tasks
- **Honoring the importance of patients' needs:** Fortrea staff aim to take time to understand the specific needs of patients, considering their ages, their community values and the needs of their families and caregivers

Reviewing the successes of Fortrea's global site support services

By providing tailored, immediate proficiency at sponsors' sites, Fortrea has helped:

- **Accelerate query resolution and overall data cleaning**, eliminating all open queries and missing pages within two months at a high-recruiting site
- **Meet database lock deadlines** by facilitating robust data cleaning and enabling analysis that led to a successful audit with no major or critical findings
- **Strengthen operational capabilities at naïve sites**, implementing effective patient engagement and achieving site performance metrics consistent with other participating sites
- **Boost patient recruitment** as sites supported by Fortrea Site Support staff consistently recruit, on average, 50% more patients and achieve enrollment milestones in half the time compared to sites without site support

As a result of multiple successes across numerous studies, Fortrea has earned a high level of satisfaction at all levels. Sponsors have repeatedly extended their contracts, sites have requested Fortrea Site Support Service staff to promote continuity and staff have chosen to remain with Fortrea after contract extensions. Ultimately, these accomplishments have translated into a high rate of satisfaction among patients as they remain engaged in their clinical trials and help move life-changing research forward.

Learn how Fortrea can provide flexible, competent staffing solutions to help overcome resource constraints and accelerate research.

fortrea.com/clinical-solutions