

Site recruitment and engagement strategies to accelerate recruitment in a cardiovascular disease study



A KEY QUESTION

What if the key to successful recruitment isn't having more sites, but knowing which sites to focus on and how to optimize their performance?

KEYWORDS

Hypercholesterolemia, Phase III Clinical Trial, Site Engagement, Patient Recruitment, Site Monitoring

Fortrea was running a sponsor's Phase III study for patients with hypercholesterolemia. This case study shares the recruitment challenges the study faced and how Fortrea strengthened its approach to complete recruitment two months ahead of schedule.

Understanding the challenge

Tasked with enrolling **300 patients** across **51 sites in the EU and U.S.** within **23 months**, Fortrea initially faced a higher-than-expected screen failure rate due to lab test results. With this early information about eligibility constraints, Fortrea collaborated with the sponsor to reset expectations, revisit site projections and provide tailored site interventions.

Taking action to enhance site recruitment

Fortrea addressed the challenge by creating a strategic plan that centered on several initial goals:

Goal	Fortrea's strategy
Increase patient awareness and understanding	As part of the pre-planned recruitment strategy, developed and distributed patient-facing recruitment materials from study start-up
Help sites identify eligible patients earlier	Utilized the pre-screening log to review site recruitment and patient pre-screening metrics, providing evidence of site engagement and continued recruitment activities
Support pre-screening activities	Planned from study start-up, the study investigator portal gave sites reference tools and eligibility checklists for quick patient review
Assist low-performing sites	Used tailored interventions based on pre-agreed metrics, with a clear escalation path for site and sponsor engagement
Reinforce protocol requirements	Sent ongoing communications (newsletters, emails and phone calls) with important study updates and alerts

With pre-agreed KPIs and triggers in place, Fortrea's Recruitment Manager continuously monitored site performance. This involved:

- **Documenting progress:** A weekly intervention tracker closely monitored recruitment
- **Identifying risks:** Performance of each site was reviewed and shared with the sponsor
- **Assigning clear actions:** A structured review of underperforming sites helped direct resources for additional engagement or inform site closure decisions, made jointly with the sponsor

Through this monitoring process, clinical research associates (CRAs) and the clinical trial lead (CTL) remained hands-on with sites as they:

- Frequently followed up on on-going pre-screening/screening activities
- Consistently communicated timelines and protocol requirements
- Shared lessons learned across sites to encourage good practices

Recognizing the results of proactive engagement

Despite the challenges, Fortrea's proactive method accelerated recruitment despite some site closures and demonstrated commitment to the sponsor. Fortrea was able to:

- Exceed recruitment expectations
- Beat the revised timeline
- Limit expenditure by focusing resources on enrolling sites

323 patients

randomized, vs.
300-patient goal

21 months

to complete recruitment,
two months ahead of the
23-month target

25% of sites

closed early, by
mutual agreement
with the sponsor

Reflecting on lessons learned

Achieving robust site recruitment performance relied on several key elements:

- **Transparent communication:** Throughout the study, consistent and open communication and monitoring proved crucial to boosting engagement between the sites, the study team and the sponsor
- **Performance monitoring:** Fortrea found that even with upfront planning, site performance varied significantly across regions. ~25% of sites were closed early due to lack of enrollment, highlighting the importance of site selection and continuous monitoring
- **Early action:** Weekly reviews helped the team make decisive and informed decisions regarding site interventions and mitigations
- **Tailored site intervention:** Fortrea flexibly reallocated its resources to help support underperforming sites and optimize sites with high potential

Ultimately, this study shows what matters most when recruitment doesn't go to plan: a CRO who spots emerging challenges early, adapts flexibly and acts decisively on real-world, site-level data, turning early setbacks into results that exceeded the original goal.

KEY TAKEAWAY

Consistent, transparent communication between the sites, the study team and the sponsor, anchored by weekly sponsor calls to review site performance and jointly agree on site engagement and interventions, kept recruitment on track and turned early setbacks into a result that beat both the enrollment goal and the timeline.



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