CASE STUDY

Navigating recruitment complexity and regional nuances in a Phase III Global Geographic Atrophy trial

A KEY QUESTION

When patient recruitment depends on understanding diverse regional healthcare landscapes and local market dynamics, how do you support enrollment success across continents?

KEYWORDS Geographic Atrophy Clinical Trial, Ophthalmology Research, APAC, Patient Recruitment, Global Recruitment, Local Nuances

Introduction

In a registrational Phase III geographic atrophy trial spanning eight countries and 50 sites across the U.S., Europe and APAC, Fortrea encountered an unexpected recruitment challenge that could have affected study timelines. While U.S. and European sites progressed as anticipated, APAC enrollment lagged significantly—not due to lack of patients, but because of fundamental differences in regional healthcare practices. In countries without established standard of care pathways for the ophthalmology disease, patients simply weren't presenting to clinics regularly, making traditional site-based recruitment strategies ineffective. Through agile leadership response, strategic vendor collaborations and sustained regional engagement, we transformed these obstacles into opportunity—completing enrollment one month ahead of schedule and randomizing 530 patients versus the 500 target. Here's how we turned geographic complexity and local healthcare nuances into pathways for global trial success.

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Addressing enrollment and retention challenges

This Phase III geographic atrophy trial presented unique patient recruitment challenges that required deep understanding of regional healthcare systems and flexible, tailored solutions. To meet the sponsor's registrational goals, the trial needed to randomize 500 patients while maintaining data quality across diverse global sites. However, what worked in Western markets proved insufficient in APAC regions:

Absence of standard care pathways in key APAC markets: In certain APAC countries, geographic atrophy had no established standard of care (SoC) treatment, fundamentally changing patient behavior. Unlike in the U.S. and Europe where patients with this disease typically maintain regular ophthalmologist visits for monitoring and emerging treatment options, as APAC patients lack a SoC treatment pathway, they had no clinical reason for routine appointments. This meant the traditional investigator referral model—where existing patients in clinic databases provide the recruitment foundation—wasn't a practicable model. Investigators rarely encountered these patients in their day-to-day practice, and when they did, these patients often weren't engaged in ongoing care. This created a recruitment paradox: Sites were selected for their ophthalmology experience, but the patient population existed outside their regular clinical flow.

Site engagement and motivation challenges: When investigators consistently fail to identify eligible patients despite significant effort, frustration and disengagement naturally follow. This risk was particularly acute in APAC, where sites had invested in study start-up activities, training and preparation, but were unable to leverage this due to patient availability issues rather than site capability problems. Maintaining investigator enthusiasm and preventing site attrition in underperforming regions required proactive communication and tangible solutions, not just encouragement.

Solutions to boost enrollment

When slower than expected enrollment trends emerged, Fortrea didn't wait for problems to escalate. We promptly organized leadership meetings to analyze regional data patterns and develop rapid-response solutions. This proactive approach enabled us to identify root causes at affected sites and implement targeted interventions before rates could threaten trial timelines and integrity.

Local recruitment vendor collaboration: In China and select APAC countries where recruitment vendors are widely used and culturally accepted, Fortrea recommended a local, qualified vendor with proven experience in ophthalmology trials and verifiable patient identification capabilities. This wasn't about outsourcing recruitment—it was about accessing patient populations through channels that matched local healthcare realities. Once approved, this vendor conducted systematic outreach to hospitals and ophthalmology clinics, identifying patients with geographic atrophy diagnoses in medical records who weren't actively seeking care. This approach effectively created the patient database that didn't naturally exist through regular clinic flow, enabling sites to screen candidates who would likely not have been identified through traditional methods.

Cross-site collaboration and learning: We implemented regular meetings among all sites globally to share lessons learned, discuss ongoing recruitment challenges and foster collaborative problem-solving. During these sessions, high-performing sites provided best practices that were working well for them—such as specific messaging that resonated with patients, effective physician referral approaches or screening process efficiencies—enabling rapid adoption across the network. This governance structure helped turn individual site successes into network-wide improvements and helped to support APAC sites in not feeling isolated in their recruitment challenges.

Targeted site support with regional engagement: At Fortrea we have a strong APAC delivery team. We maintained close collaboration and communication between Fortrea, investigators and recruitment vendors through weekly meetings and onsite booster visits. In Taiwan, we worked closely with investigators to support patient screening despite high screen failure rates. In Australia, we conducted regular meetings with investigators and study coordinators to help maintain motivation and engagement throughout the study duration.

Real-time monitoring and proactive intervention: We programmed Quality Tolerance Limits (QTLs) to closely monitor enrollment rates, screen failure patterns and protocol deviations across all sites. This enabled data-driven decision-making about where to focus support resources, which sites needed additional training or encouragement and when enrollment strategy adjustments were necessary. Early warning systems were critical to maintaining enrollment targets and preventing small regional delays from becoming major timeline threats.

Results: Ahead-of-schedule enrollment and global study success

By completing last patient randomization one month ahead of schedule, Fortrea successfully exceeded the sponsor's timeline expectations despite significant regional recruitment challenges. The trial randomized 530 patients versus the 500 target, helping to provide an additional buffer against attrition and protecting data integrity for registrational submission.

Perhaps most importantly, we successfully activated and maintained engagement across 50 sites in eight countries spanning the U.S., Europe and APAC—proving that with flexible, regionally tailored approaches and proactive problem-solving, even complex global ophthalmology trials can deliver on aggressive timelines.

Leverage Fortrea's extensive trial experience

With deep experience in complex therapeutic areas and a commitment to patient-centric trial design, Fortrea's Ophthalmology team can bring tailored solutions that support smarter enrollment and sustained engagement across global markets. Our proactive approach to regional operational excellence aims to help sponsors run more efficient, compliant trials.

For more information on how Fortrea can accelerate your ophthalmology research, contact our team today.

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