Questions & Answers

Ophthalmology gene therapy trial:

Insights from a Senior Clinical Project Manager

At Fortrea, we recognize that the deep knowledge and leadership of our delivery teams are fundamental to driving innovation and delivering results for our sponsors.

Clinical project management is fundamental to ophthalmology research

In the evolving landscape of ophthalmology clinical research, the role of the clinical project manager is pivotal. These professionals serve as the linchpin between sponsors, sites, vendors and patients—ensuring that complex studies are delivered efficiently, compliantly and with a focus on quality. Their ability to coordinate multidisciplinary teams, navigate regulatory requirements and maintain clear communication is essential to the success of any clinical trial.

Adam Sgarlata

Adam Sgarlata, Senior Clinical Project Manager, is a clinical research leader with over 15 years of experience managing ophthalmology trials across Phases I-IV; whose leadership and experience have played a key role in expanding our ophthalmology gene therapy trial portfolio. With deep experience in driving site engagement, patient recruitment and vendor oversight, he is passionate about translating scientific innovation into operational execution.

Questions & Answers with Adam Sgarlata

Adam, can you provide an overview of the ophthalmology gene therapy program and your background?

Absolutely. I've been in clinical research for 15 years, with a focus on retinal studies and global project management. Our current program is a suite of gene therapy studies for neovascular age-related macular degeneration, all running across about 90 sites in the U.S. What's unique is that many of these sites participate in multiple studies, which lets us drive real efficiencies.

What was the biggest challenge you and your team faced in launching the ocular gene therapy trial?

The studies kicked off right in the middle of the pandemic, and we were asking sites—many of them completely new to gene therapy—to take on this large gene therapy dosing program. The regulatory and practical hurdles were significant—not just Institutional Review Board (IRB) approvals, but also institutional biosafety committees, complex storage and administration protocols, and a steep learning curve for everyone involved.

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How did Fortrea help sites overcome these challenges?

We leaned into our long-standing relationships with high-performing retina sites. Because we'd worked with many of these clinics before, we knew their capabilities and could move quickly through the start-up process. But the real difference was our hands-on support. Our in-house and field CRAs spent hours working with and training site staff, helping them get certified on imaging and study procedures, and making sure they had the equipment and confidence to run these studies effectively with everything they needed. Our start-up team worked closely with study coordinators to help educate and navigate the National Institutes of Health (NIH) Institutional Biosafety Committee (IBC) registration process from start to finish—especially as staff turnover was high during the pandemic and communication was complex.

We also built a robust communication network. Sites always knew who to call, and I made sure my number was available if they needed help fast. It's a small-team feel with big-team backing—agile, responsive and always ready to jump in and solve problems.

What differentiates Fortrea in managing complex ophthalmology gene therapy trials like this?

Adaptability and collaboration. We started with just one study and quickly scaled to six, adding new cohorts, increasing sample sizes and complexities as the program grew. Our teams are nimble—we pivot fast to reduce the burden on sites and keep the lines of communication open. We also work closely with vendors, from imaging to equipment, to make sure every piece fits together seamlessly and sites are able to receive, manage and properly administer the test material, which, in terms of gene therapy studies, required a lot of additional cold-chain logistics, safety protocols and education to the site staff.

Can you share a moment where collaboration made a real difference?

There were plenty, but one stands out. When sites faced sudden staff change, our team jumped on calls with each of the sites to train new coordinators and staff to get them up to speed with the studies and quickly got them certified. That kind of responsiveness kept the trial and site on track and built trust with our clients.

What advice would you give to sponsors planning similar trials?

Invest in relationships and communication. The science is complex, but it's the people and the process that make or break a study. Be ready to support sites and the patients at every step, and don't underestimate the value of a team that's willing to roll up their sleeves and solve problems together.

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>
> **A. Sgarlata**

Any final thoughts on the patient experience in gene therapy trials?

Gene therapy brings new hope, but it also brings complexity—especially for patients. Some routes require surgical administration and extra aftercare, while others are less invasive. Our job is to reduce the burden wherever possible, making sure patients and their caregivers are informed and feel supported every step of the way. At the end of the day, vision is everything for these patients, and we never lose sight of that.

Interested in hearing more about how our team can accelerate your ophthalmology clinical research – contact us

LEARN MORE about the ophthalmology offering at Fortrea.com

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