CASE STUDY

Collaborative practices advance an ultra-rare ophthalmological disease clinical trial

Running a rare disease clinical trial requires building and maintaining strong connections between a sponsor, sites, advocacy groups and patients. This case study shares how Fortrea applied its ophthalmological, rare disease and operational expertise to promote collaboration and help a biotech sponsor advance its Phase III study.

Challenges faced	Solutions implemented
Managing a transition Fortrea (then known as Covance) had recently acquired another CRO (Chiltern) to expand its biotech reach. They assumed responsibility for a sponsor's rare ophthalmological disease study, which was already in the startup phase.	**Quickly identifying needs** The Fortrea team assigned an experienced Project Manager (PM) to the study. The PM worked to understand and align with the sponsor's culture, needs and goals.
Partnering with sites The sponsor had already selected 29 sites in 11 countries across the Americas and Europe/Middle East before Fortrea assumed responsibility of the study.	**Enabling transparency** Fortrea aimed to establish strong site relationships and started to set up frequent contact points. With regular communication, Fortrea collected updates on patient screening progress, communicated enrollment status across the sites and made informed enrollment projections.
Recruiting for an ultra-rare disease study Fortrea understood the challenges of finding qualified study participants in a competitive space.	**Engaging an advocacy group** To strengthen their recruitment strategy, the site engaged with a patient-led advocacy and support group and increased the visibility of the study.

Fortrea

Recognizing the results

Fortrea's efforts to forge relationships with the sites and an advocacy group created a high level of participant interest in the study. As a result, recruitment was exceeded by approximately 20% of the sponsor's original target and the sites were able to accommodate and enroll the additional participants. The sponsor was especially pleased with Fortrea's statistics and medical writing teams to support an on-time database lock (DBL).

Based on the study's results, the sponsor received an orphan drug designation for their treatment from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). The sponsor continues to advance research and hopes their treatment will address a serious unmet medical need for people living with this rare disease.

Together, let's navigate the complexities of rare disease trials.

LEARN MORE at fortrea.com

Fortrea