A first-in-class drug's journey to market

An ophthalmology case study with Apellis

Apellis Pharmaceuticals, a growing biopharmaceutical company, wanted to investigate the efficacy of SYFOVRE® (pegcetacoplan injection) to treat patients with geographic atrophy (GA), an advanced form of dry age-related macular degeneration. A leading cause of blindness, GA affects more than 5 million people worldwide and 1 million in the United States alone. This targeted C3 therapy helps regulate excessive activation of the complement cascade within the immune system, a known contributor to the progression of many serious diseases. The implemented development plan for SYFOVRE® consisted of two global Phase III studies across 15 countries in over 200 sites worldwide, with an additional open-label extension study that was awarded later. The complexities of the trials required a contract research organization (CRO) partner with global reach, scalable solutions and excellent project and data management, which is why Apellis turned to Fortrea for support.

Delivering on the data cut request

As the study approached a critical milestone, Apellis submitted a request to Fortrea for a data cut across the program. The request? Deliver data cut in a month. To meet this request, Fortrea leadership took immediate steps to develop a timeline with tight target delivery dates, increased staffing support for data management, organized daily internal and external meetings and collaborated even more closely with vendors and sites.

The executed strategy included:

- Assessed routine deliverables to focus the full global team on the required critical data points of the data cut
- Tailored reporting to focus on the needs of the sponsor to reach the deliverable
- Frequent status updates among team members and leadership to ensure on-time delivery of the data cut
- Daily calls to the sponsor providing latest communication and status

KEY TAKEAWAYS

Managed two full-service Phase III ophthalmology studies across 15 countries and over 200 clinical sites

Satisfied sponsor request for data cut in a month

Saved time in sponsor's New Drug Application for first-ever treatment for geographic atrophy patients who had no treatments available

Fortrea

Undaunted by the task, Fortrea scaled its global resources and engaged project management leads to collaborate tirelessly across worldwide time zones in support of the sponsor's request. The cut was delivered as requested by the target date, inspiring new confidence in Fortrea's capabilities and commitment to excellence.

According to Jason Raines, senior vice president of Development Operations at Apellis, "We requested tight timelines. We needed this data cut in the timing we asked for to support our mission and I appreciated the can-do attitude that was shown. Fortrea came to the table with problem-solving in mind."

Combining flexibility with operational agility for data-driven results

Many biotech companies choose not to partner with global CROs due to concerns of deprioritization. However, this was not the case with the sponsor. Fortrea's mission to be more than a partner in the sponsor-CRO relationship drives dedicated collaboration, no matter the size or volume of business.

"Our concern when selecting a large CRO partner was that we wouldn't get as great of a service because of our size," Apellis said. "But we got the care we needed. Apellis and Fortrea built a true partnership that has delivered multiple and critical milestones which simply could not have been done without great team communication, organizational agility, scalability in terms of people, processes, and systems and a global footprint. Fortrea excels at planning, risk assessment and mitigation, and functional collaboration."

Pioneering life-changing treatment for patients

Thanks to Apellis and Fortrea partnership's speedy delivery of the data cut, Apellis successfully met its critical deadline and SYFOVRE® was approved by the FDA as the first-ever treatment for geographic atrophy. This partnership highlighted how every day saved in clinical trials is not just a day saved in time and costs to the sponsor, but also a day closer to potentially delivering a medical breakthrough—and new hope—to patients in need of innovative healthcare solutions.

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