

CLINICAL CASE STUDY

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 pegcetacoplan 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 investigational 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 pegcetacoplan 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 Labcorp for support.

Delivering on the data cut request

As the study approached a critical milestone, Apellis submitted a request to Labcorp for a data cut across the program. The request? Deliver data cut in a month. To meet this request, Labcorp 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 client 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 client providing latest communication and status

Undaunted by the task, Labcorp 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 Labcorp's capabilities and commitment to excellence.



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 potential first-ever treatment for geographic atrophy patients who currently have no treatments available.



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. Labcorp 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 Apellis. Labcorp’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,” Raines said. “But we got the care we needed. Apellis and Labcorp 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. Labcorp excels at planning, risk assessment and mitigation, and functional collaboration.”

Pioneering life-changing treatment for patients

Currently, there are no approved treatments for geographic atrophy. Pegcetacoplan has the potential to be the first drug of its kind to approach commercialization, showing promise by slowing the growth of lesions which lead to retinal cell deterioration for patients with GA.

Thanks to the Apellis and Labcorp partnership’s speedy delivery of the data cut, Apellis successfully met its critical deadline and has now also submitted a New Drug Application for the investigational therapy. 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.

Learn more at drugdevelopment.labcorp.com