CASE STUDY

Accelerating APAC region clinical ophthalmology trials

A KEY QUESTION

How can sponsors accelerate clinical trial timelines when unexpected challenges arise?

KEYWORDS Ophthalmology, APAC, Dry Eye Syndrome, Clinical Development, Patient Enrollment, Site Engagement, Operational Agility

Drawing on our 30+ year CRO heritage of Fortrea, formerly as part of Covance and Labcorp Drug Development, including all of the ophthalmology experience gained during the 2017 acquisition of Chiltern, we collaborated with a rapidly growing biotech in China to advance their ophthalmology program. This case study illustrates how our ophthalmology experience, great engagement with local sites and investigators and agile approach to regional operations provided the multifaceted capabilities to facilitate our collaborator's dry eye syndrome pipeline development.

Key highlights

In this ophthalmology trial, several key learnings emerged, highlighting the importance of transparent communication, the role of flexibility at a global level and foundational elements of follow-through and trust.

- **Effective communication:** Maintaining open communication with the sponsor and being sensitive to their commercial strategy is vital
- **Agile approach:** Fortrea's ability to adapt processes and mobilize resources swiftly is crucial in navigating unexpected challenges
- **Trusted collaboration:** Building trust through swift, personalized attention and action is essential for success in clinical trials

Fortrea

The challenge

Fortrea faced several challenges during this collaboration:

1. **Restrictions and shortages during COVID-19 lockdown:** Enrolling patients became challenging during the COVID-19 lockdown period, with on-site visit restrictions and site resource shortages. As this was an ophthalmology study, patients needed to access the clinic in order to undergo the assessments and tests required for patient monitoring and the study endpoints.
2. **Last patient in (LPI) impact:** The national COVID-19 outbreak in China from November 2022 to January 2023 significantly affected the study's LPI target.
3. **Sponsor's commercialization strategy shift:** Our client's timelines changed due to critical go-to-market strategies for their current pipeline, which would determine the success of commercialization in the local market. Major changes included moving the clinical study report (CSR) final submission deadline to three months ahead of the original plan.

Customer focus: Our unwavering commitment

These challenges required quick thinking and a laser-like focus on customer needs:

Fortrea's actions and solutions

Fortrea's team responded to these challenges with agility and efficiency, proactively managing the situation to minimize disruption to the LPI target. Additionally, in response to the sponsor's strategy shift, Fortrea mobilized cross-functional teams, optimized internal processes and customized procedures to meet the accelerated CSR submission timeline.

Close communication and engagement with ophthalmology sites and staff: With considerable planning and supervision, clinics were made accessible to patients for assessments and monitoring visits were conducted, thus maintaining the project momentum despite the COVID-19 restrictions.

Excellence in local operation: A strong, capable ophthalmology-experienced team, based in China, took responsibility and with a "make it possible" attitude and scrupulous execution planning, the team successfully delivered the project.

Strategic guidance and services provided

In response to the sponsor's request for an accelerated CSR submission, Fortrea provided critical strategic guidance and services:

- Escalated to senior management and functional heads for timely support
- Developed a detailed daily work breakdown and feasibility evaluation
- Collaborated with the sponsor to achieve the database lock (DBL) target ahead of schedule
- Adjusted data management, clinical monitoring and CSR timelines to expedite the process
- Facilitated budget negotiations to achieve agreement

The success story

Fortrea's collaborative efforts supported the timely CSR submission, accelerating the product launch for our APAC collaborator. Our client expressed extreme satisfaction with the study delivery—particularly the final CSR delivery. This collaboration has built a trusted relationship between Fortrea and our Chinese collaborator.

Conclusion

In summary, our ophthalmology capabilities, agility and commitment to customer experience proved essential to our collaborator's success. Through swift and sure adjustments achieved through collaborative efforts, Fortrea and our APAC region collaborator overcame challenges, expedited timelines and delivered results. This case stands as an example of both our operational capabilities and dedication to advancing ophthalmology trials—no matter the obstacles.

Your next steps

Discover how Fortrea can accelerate your ophthalmology trials and help you progress toward your clinical development goals.

Together, exceptional is possible
Talk to Us

LEARN MORE at fortrea.com

Fortrea