Transitioning a Phase III Age-related Macular Degeneration Clinical Trial

Our client turned to UBC, trusting our transition of their currently active study would ensure continuity, enhanced site and ophthalmologist engagement, and operational excellence in collecting quality, valuable data.

UBC is currently managing a phase III clinical trial for treatment of patients with age-related macular degeneration. This safety and efficacy study investigates a new dosing schedule for a product that is currently commercially approved for a different dosing regimen. This study is being conducted at 70 sites across the US with a target population of at least 500 patients 60 years of age and older.

SITUATION / CHALLENGES

UBC was contracted by a large pharmaceutical company to transition their ongoing study after site selection was complete since the current vendor was not able to offer adequate site support. UBC implemented a transition plan and established strong relationships with the previously selected ophthalmology sites within 6 weeks.

Challenges presented themselves in multiple areas:

- **Site Engagement & Communication**

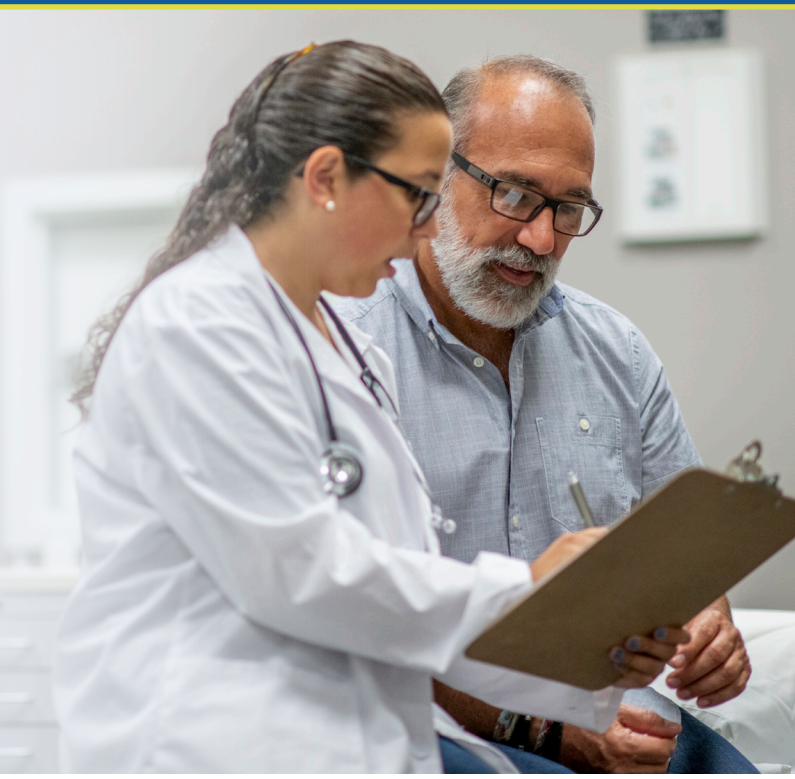
  The ophthalmology sites were becoming disengaged because of minimal program communication and delayed or missed payments.

- **Patient Barriers to Involvement**

  This study involves older, ocularly impaired patients so transportation to the investigational site can be difficult.

- **Global Public Health Crisis**

  The study was already fully launched nationwide when the global health crisis resulted in mandated site closures and implementation of social distancing measures.



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APPROACH

UBC quickly implemented effective actions to ensure clinical trial continuity and maximize efforts in data collection. UBC executed an efficient study transition while simultaneously accelerating the trajectory of site activation and patient enrollment. We did this by incorporating the following strategies:

Developed strong relationships with study sites

- We worked hand in hand with the sponsor to develop a multi-step contact plan to notify all sites of the change in clinical research organization and transitioned all necessary study documents to UBC.
- UBC contacted each site to quickly establish baseline performance and clear contact points, and to introduce UBC's capabilities and role.
- Site relationships were strengthened by initiating monthly study update meetings. These meetings formed the basis for overall clinical trial review, congratulating sites on meeting milestones, and communicating updates on protocol amendments.

Maximizing engagement with ophthalmologists and sites through an organized and meticulous operational approach

- UBC supported the study sites in two ways: a traveling team who visit every 6 – 8 weeks, as well as an in-house team who are available to respond to questions, issues or concerns via telephone or email. This ensured that each site was set up with a robust support team to ensure immediate resolution.
- By utilizing our concierge service, patients were provided easy transportation to the sites, eliminating a significant barrier to patients' participation. UBC established deep cleaning procedures and PPE protocols to ensure safe transportation to the site.

Providing the sponsor and sites with tools to drive enrollment and completion

- Remote monitoring was implemented during the pandemic to successfully navigate study requirements and complete an interim analysis as scheduled.
- UBC provided materials to site staff to promote referrals from other HCPs as well as reinforced training.

RESULTS

UBC's site engagement and communication methods set our service apart from the prior vendor and exceeded the sponsor's expectations and improved sites' satisfaction with the study. Through our operational excellence, ophthalmologists were kept motivated and educated throughout the study.

UBC

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