CASE STUDY

ophthalmology

STUDY SPECIFICS

Indication: Neovascular AMD (age related macular degeneration)

Study Phase: Phase III

Primary Endpoint: Mean change in visual acuity from baseline to month 12 visit

Patient Population: 622 patients

Regions: Argentina, Australia, Austria, Brazil, Canada, Colombia, Croatia, Czech Republic, Estonia, Finland, France, Germany, Hungary, Israel, Italy, Latvia, Norway, Poland, Portugal, Spain, US

Number of Sites: 226

TFS Services: Feasibility/site qualification, start-up (including site contracts/submissions, certifications), site management, project management and TMF

Enrollment Period: 18 months

Treatment Period: 24 months

CONTEXT

A phase 3 combination study investigating the safety and efficacy of intravenous injection of IMP or sham administered in subjects with subfoveal neovascular AMD. The sponsor was a small US biotech developing innovative treatments for patients with orphan or inherited retinal diseases with significant unmet medical needs.

CHALLENGES

- The sponsor instigated numerous strategic changes during the life of the study, including a significant expansion of 16 new countries, which triggered rapid changes in TFS' management and delivery strategy.
- This was a complicated study to enroll, mainly due to baseline and Day 1 visual acuity needs, resulting in a 50% screen failure rate, which led to a very slow and lengthy enrollment phase.
- The protocol design required strict masking procedures; separating a small injecting team led by the PI.
- It was a particularly challenging start-up period due to many sites having to focus on the completion of lengthy certification activities, as well to ensure site contracts were completed and executed on time.
- Performing a 12-month interim analysis on time was also challenging, to ensure the high global volume of patient data was clean, which occurred during a summer vacation period.

TFS SOLUTION

- TFS developed the initial feasibility strategy resulting in 6 brand new countries being introduced to the sponsor's program and their network. 12 months on, 16 additional countries were transitioned into the study. These countries strategically rolled over into this study following completion of enrollment on two other studies in the same program. To ensure smooth and efficient transition,

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TFS worked in alignment with the sponsor, ensuring contracts and budgets were transferred into new templates and ensuring grandfathering of sites occurred in a timely manner, leveraging much experience from previous studies, as well as the earlier phase of the project.

- Due to strategic changes made by the sponsor, our study team worked in start-up for more than 18 months as new countries were introduced over three phases. In parallel, the recruitment and treatment phase was ongoing in the earlier initiated countries. This meant many changing priorities for the TFS study team, so a restructure and reassignment of activities was carefully and strategically implemented, to ensure all priorities were sufficiently resourced, within the agreed timelines.
- TFS carefully considered the age of the patient population needs (> 50 years). As well as travel reimbursement, some older patients were even accommodated with ambulatory care to ensure compliance of the study visit schedule. Investigators also acknowledged the importance to only screen and randomize eligible subjects that could complete the 24-month visit schedule.
- TFS CRAs performed booster visits at some challenging sites, to provide encouragement with completion of certification/grandfathering, enrollment and data cleaning, ensuring activities were completed on time.
- The sponsor was somewhat flexible with study design in terms of length of the screening period towards the end of the study enrollment period, as well as a more flexible approach to patient visit schedule. Patient retention and compliance to the protocol would have been compromised if these two points had not been evaluated.
- An intense period of data cleaning to support the 12-month interim analysis was managed in line with the sponsor's expectations. Sites were prepared and clear expectations regarding the data management strategy were communicated ahead of time. This advance planning ensured sites had time to re-evaluate resources, especially during the summer months. TFS also ensured contingent CRAs were available to support oversight during primary CRA absence during this period.

CLIENT ADVANTAGE

- Careful initial site selection and management of sites by TFS ensured that enrollment was met one month ahead of schedule.
- The positive site experience with TFS and the sponsor meant that sites were keen to participate in further studies.
- Due to the high quality performance, on-time delivery, regulatory expertise, trusting proactivity and flexibility of resources, TFS continues to be awarded further studies from this client.