TFS HealthScience
Clinical Research Excellence

Geographic Atrophy (GA) Secondary to Dry Age-Related Macular Degeneration

Case study

Context

TFS was selected to perform **full-service clinical operations** and project management, including site contracts, ethics submissions, regulatory, and other clinical study start-up activities. Start-up tasks for this study included **specialized processes** to be undertaken at the site level, such as visual acuity and SD-OCT requiring associated digital systems and certified technicians.

The sponsor is an innovative biopharmaceutical company focused on the **discovery** and **development** of treatments for retinal diseases with significant unmet medical needs.

Study specifics

Drug class

Pegylated RNA Adapter
via intravitreal injection

Patient population

Aged 50 years or greater

Countries

US, Canada, Israel, Czech Republic, Hungary, Croatia, Latvia

Primary endpoints

Mean rate of change in GA over 12 months measured by fundus autofluorescence (FAF) at three time points: Baseline, Month 6 and Month 12

Study phase

II B

Number of patients randomized

286

Number of Sites

78

Treatment period

18 months

Challenges

- **Screen failure rates** for this indication are >50%.
- The **COVID-19** pandemic imposed travel restrictions that varied by country and regional level.
- The **strategy** was changed and expanded during the early stages of trial start-up to ensure the study population was met.

TFS Solution & Benefits

TFS has **experience** from previous retinal disease trials, particularly in this indication, and long-standing relationships with experienced sites. Despite changes to the strategy during the early stages of start-up and an expansion, sites were initiated in a timely manner. The clinical research team and sites leveraged a project change management process and maintained close collaboration to **stay on track** with the new sponsor strategy.

The **global pandemic** brought many unprecedented challenges to the team and study delivery. In anticipation of deviations occurring, TFS formalized a specific **COVID-19 risk plan**, aligning with the sponsor with respect to ongoing patient safety, treatment protocols, and remote monitoring strategies to ensure protocol compliance and data integrity. The challenges were overcome **following guidance** from the TFS COVID-19 Ramp to Recovery Team and in line with global regulatory guidance.

Despite the high screen failure rate, the study was delivered **successfully** with minimal input from the sponsor.

TFS' expertise and skillful planning has secured the Phase III program in this **unmet disease area**, further developing the relationship with the client and TFS' site network.

About TFS

TFS HealthScience is a global Contract Research Organization (CRO) that supports biotechnology and pharmaceutical companies throughout their entire clinical development journey. In **partnership** with customers, we build **solution-driven teams** working for a healthier future. Bringing together nearly 700 professionals, TFS delivers **tailored clinical research services** in more than 40 countries and supports customers with **comprehensive solutions** through three strong business models: Clinical Development Services (CDS), which provides full-service support at all stages of the clinical development process, Strategic Resourcing Solutions (SRS), which offers expert insourcing and targeted recruitment services, and Functional Services (FSP), to provide customers with strategic workforce management solutions.

700

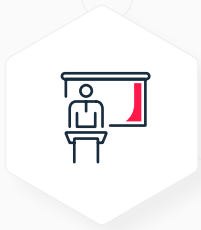
Nearly 700
Worldwide
professionals

40

Conducting trials
in more than
40 countries

17

Offices and legal
entities in
17 countries



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Industry leading
expertise in
4 major areas

Detailed information about TFS, and its business offerings can be obtained through **www.tfscro.com.**