Verana Health

CASE STUDY

CERSI UCSF-Stanford | American Glaucoma Society | American Academy of Ophthalmology | FDA

Trial Monitoring & Patient Reported Outcomes for PRO-MIGS Study

Verana partnered with U.S. Food & Drug Administration's (FDA), Center of Excellence in Regulatory Science and Innovation (CERSI) from UCSF and Stanford, American Academy of Ophthalmology and American Glaucoma Society (AGS) will develop a patient-reported outcome (PRO) instrument called the Glaucoma Outcomes Survey (GOS) that can be used for future FDA submissions for MIGS devices.

Background

- There is a gap in MIGS research as to how MIGS affects patient experience or perception of their glaucoma
- PRO-MIGS study assessed patient concerns about glaucoma before and after undergoing MIGS.

Objective

Verana Health helped identify patients for prospective evidence generation regarding QOL before and after undergoing MIGS

The PROMIS and GOS QOL surveys were administered to patients prior to MIGS and 3 months after surgery.

Results

Overall, there was a large positive group change in QOL after MIGS procedures. The relationship between these changes and clinical data elements, including IOP and visual acuity, was assessed in this study.

Algorithm Development

Identified eligible patients by site & procedure volume by site

Patient Identification

3.7M

Patients with primary open-angle glaucoma

Patient Enrolled

191

Participants enrolled in study

Site Monitoring

Monitored enrollment

Data Source to Identify Practices

IRIS Registry Data

Sources: https://www.healio.com/news/ophthalmology/20210901/blog-leveraging-big-data-of-patientrecorded-outcomes-for-promigs-study and https://veranahealth.com/verana-health-fda-cersi-the-american-academy-of-ophthalmology-and-the-american-glaucoma-society-announce-the-start-of-a-new-patient-reported-outcomes-validation-study/