REGENERON
SCIENCE TO MEDICINE®

Ophthalmology Areas of Interest

(Investigator Initiated Studies and Research Collaborations)

Investigator-initiated studies (IIS) and collaborative studies may be supported by Regeneron and include clinical trials of approved and investigational uses of Regeneron medicines, including medicines approved by the FDA or still in development.

The following study types may be considered:

- Interventional, non-interventional, observational, cohort, retrospective analyses, and real-world evidence (RWE) studies to address clinical data gaps
- Testing and validation of tools, methodologies, and processes

Topics relevant to aflibercept 2 mg and 8 mg

A. Studies to investigate and optimize measurement of anatomical and visual functions in chorioretinal vascular diseases
   i. Alternative methods of disease monitoring in addition to those routinely used in past or current phase 3 trials (OCT-A, UWF angiography, home monitoring, volumetric analyses, use of other functional outcomes, contrast, microperimetry, LLD, peripheral field, etc.)
   ii. Quantification of disease-modifying effects such as sight-threatening events, ischemic index, vascular architecture, etc.
   iii. Artificial intelligence/machine learning for optimizing diagnosis and monitoring of retinal vascular diseases

B. Predicting treatment response
   i. Artificial intelligence/machine learning initiatives aimed at predicting treatment response
   ii. Identification of novel ocular and/or systemic characteristics, anatomic endpoints, biomarkers, genetics, patient-reported outcomes/QOL and indicators of disease progression

Select studies related to aflibercept 2 mg

A. Studies with aflibercept 2 mg in combination with alternative retinal photocoagulation strategies in DR for optimal management of DR as a pan-retinal disease
B. Real-world studies, particularly those evaluating patient-reported outcomes (PROs) and quality of life (QOL) in patients treated with aflibercept across all indications

Select studies related to aflibercept 8 mg (would only commence after FDA approval)

A. Studies evaluating outcomes with aflibercept 8 mg in sub-populations of patients with nAMD or DME
   i. Patients with prior treatment (ie, switching)
   ii. Exploring alternative dosing regimens (ie, Q4-8, T&E, no loading dose)
B. Studies evaluating outcomes with aflibercept 8 mg in CNV other than nAMD (ie, those not included in existing or planned aflibercept phase 3 and phase 4 studies)
C. Studies evaluating outcomes in underserved populations and under-represented populations in existing or planned phase 3 and 4 studies.

Note: Studies comparing aflibercept with other anti-VEGF agents will be out of scope.