

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

Aflibercept 8 mg

General aspects

- 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, 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 and/or functional endpoints, biomarkers, genetics, patient-reported outcomes/QOL and indicators of disease progression

Outcomes

- A. Studies evaluating outcomes with aflibercept 8 mg in sub-populations of patients with nAMD or DME or MEfRVO.
- 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)

Representation and Real-world experience

- A. Studies evaluating outcomes in underserved populations and under-represented populations
- B. Real-world studies, particularly those evaluating patient-reported outcomes (PROs) and quality of life (QOL) in patients treated with aflibercept across all indications
- C. Real-world experience with aflibercept 8mg

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