

## Clinical Trials at the Retina Partners

The Retina Partners are committed to advancing the treatment of a variety of retinal conditions. Our physicians and research staff take pride in our involvement in national studies across multiple disciplines to bring the latest treatment options to our patients.

We are dedicated to providing the highest quality of care to our research participants and offer our patients potential options for new and improved treatments for retinal diseases.

We believe our research work in clinical trials will aid better treatment and outcomes for retinal conditions leading to an improved quality of life for our patients.

### **What are the benefits of conducting a clinical trial?**

A clinical trial is a research study conducted on participants with the goal of answering specific questions about new drugs, devices, diagnostics or treatments.

Our patients participate in clinical trials for the potential to benefit from a new drug or treatment procedure, improved management of symptoms and the opportunity to contribute to the future advancement of vision care.

### **What are the different phases of a clinical trial?**

Clinical trials are conducted in a series of different phases each designed to answer a separate research question.

**Phase I:** Researchers test a new drug or treatment in a small group of patients to evaluate its safety, determine a safe dosage range, and identify side effects. Phase I trials aim to find the best dose of a new drug with the fewest side effects.

**Phase II:** The drug or treatment is given to a large group of patients to see if it is effective and to further assess its safety. Patients are closely watched to see if the drug works. If a drug is found to work, it can be tested in a phase III clinical trial.

**Phase III:** The drug or treatment is given to larger groups of patients to confirm its efficacy, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely. Phase III trials compare a new drug to the standard-of-care drug. These trials assess the side effects of each drug and which drug works better. Phase III clinical trials are often needed before the FDA will approve the use of a new drug for the general public.

**Phase IV:** Studies are done after new drugs are approved by the FDA or treatments have been marketed to gather information on its effectiveness in various populations. The drug is tested in several hundreds or thousands of patients. This allows for better research on short-lived and

long-lasting side effects and safety. Physicians can also learn more about how well the drug works and if it's helpful when used with other treatments.

### **What are the benefits of participating in a clinical trial?**

Clinical trials provide patients a promising new treatment or the best available conventional treatment. Clinical trials have demonstrated to offer some of the most advanced retinal treatments available today.

### **Can I participate in a clinical trial?**

If you want to learn if you are an eligible candidate to participate in a clinical trial, speak with one of our physicians at your next appointment or contact us at (877) 3-RETINA.

To learn more about clinical trials, please visit <http://www.clinicaltrials.gov>.

### **What clinical trials are available at The Retina Partners?**

We are involved in the following trials:

Click here to view a PDF version of this information.

#### **Wet Macular Degeneration Clinical Trials**

##### **SANDOZ**

A 52-Week Multicenter, Randomized, Double-Masked, 2-Arm Parallel Study to Compare Efficacy, Safety and Immunogenicity Of SOK583A1 To Eylea®, Administered Intravitreally, in Patients with Neovascular Age-Related Macular Degeneration

Status: Enrollment Opening Soon

##### **LONGITUDE**

A Longitudinal, Biomarker Study, to Explore the Composition of Aqueous Humor and the Associated Multimodal Retinal Imaging in Anti-Vegf Treatment-Naïve Neovascular Age-Related Macular Degeneration and Diabetic Macular Edema, Before and After Aflibercept Treatment

Status: Enrollment Opening Soon

##### **AVONELLE-X**

A Multicenter, Open-Label Extension Study to Evaluate the Long-Term Safety and Tolerability of Faricimab in Patients with Neovascular Age-Related Macular Degeneration

Status: Closed To Enrollment

#### XPLORE

A Phase III, Double-Blind, Parallel Group, Multicenter Study to Compare the Efficacy and Safety of Xlucane Versus Lucentis in Patients with Neovascular Age-Related Macular Degeneration

Status: Closed To Enrollment

#### CHENGDU

A Phase III, Multicenter, Double-Masked, Randomized, Dose-Ranging Trial to Evaluate the Efficacy and Safety of Conbercept Intravitreal Injection in Subjects with Neovascular Age-Related Macular Degeneration (AMD) (PANDA-2)

Status: Closed To Enrollment

#### GRAYBUG

A Phase 2b Multi-Center Dose-Ranging Study Evaluating the Safety and Efficacy of a Long-Acting Intravitreal Sunitinib Malate Depot Formulation (GB-102) Compared to Intravitreal Aflibercept in Subjects with Neovascular (Wet) Age-Related Macular Degeneration

Status: Closed To Enrollment

#### CANDELA

A Randomized, Single-Masked, Active-Controlled Phase II Study of the Safety, Tolerability, and Efficacy of Repeated Doses of High-Dose Aflibercept in Patients with Neovascular Age-Related Macular Degeneration

Status: Closed To Enrollment

#### TENAYA

A Phase III, Multicenter, Randomized, Double-Masked, Active Comparator-Controlled Study to Evaluate the Efficacy and Safety of Faricimab in Patients with Neovascular Age-Related Macular Degeneration

Status: Closed To Enrollment

#### PORTAL

A Multicenter, Open-Label Extension Study to Evaluate the Long-Term Safety and Tolerability of the Port Delivery System with Ranibizumab in Patients with Neovascular Age-Related Macular Degeneration

Status: Closed To Enrollment

#### ARCHWAY

A Phase III, Multicenter, Randomized, Visual Assessor-Masked, Active-Comparator Study of the Efficacy, Safety, And Pharmacokinetics of the Port Delivery System with Ranibizumab in Patients with Neovascular Age-Related Macular Degeneration

Status: Closed To Enrollment

CEDAR

A Phase III Study to Assess the Safety and Efficacy of Abicipar Compared with Ranibizumab in Treatment-Naive Patients with Neovascular Age-Related Macular Degeneration

Status: Closed

AVENUE

A Phase II Study to Investigate the Safety, Tolerability, Pharmacokinetics, and Efficacy of RO6867461 Administered Intravitreally in Patients with Neovascular Age-Related Macular Degeneration

Status: Closed

OPTHEA

A Dose-Ranging Study of Intravitreal OPT-302 in Combination with Ranibizumab, Compared with Ranibizumab Alone, in Participants with Neovascular Age-Related Macular Degeneration (Wet AMD)

Status: Closed

LADDER

A Phase II Study to Investigate the Efficacy and Safety of the Ranibizumab Port Delivery System for Sustained Delivery of Ranibizumab in Patients with Subfoveal Neovascular Age-Related Macular Degeneration

Status: Closed

ONYX

A Randomized, Double-Masked, Active-Controlled Phase 2 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal REGN910-3 in Patients with Neovascular Age-Related Macular Degeneration

Status: Closed

### **Dry Macular Degeneration Clinical Trials**

GALLEGO

A Phase II, Multicenter, Randomized, Single-Masked, Sham-Controlled Study to Assess Safety, Tolerability, and Efficacy of Intravitreal Injections of FHTR2163 in Patients with Geographic Atrophy (GA) Secondary to Age-Related Macular Degeneration (AMD)

Status: Open For Enrollment

GENENTECH\_GR42163

A Phase 1a, Multicenter, Open-Label, Single-Dose, Dose-Escalation Study of the Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Intravitreal Injections of RO7303359 in Patients with Geographic Atrophy (GA) Secondary to Age-Related Macular Degeneration (AMD)

Status: Open For Enrollment

NGM621-GA-201

A Phase 2 Multicenter, Randomized, Double-Masked, Sham-Controlled Study of the Safety and Efficacy of Intravitreal Injections of MGM621 in Subjects with Geographic Atrophy (GA) Secondary to Age-Related Macular Degeneration (AMD)

Status: Open For Enrollment

GALLEGOLE

A Multicenter, Open-Label Extension Study to Evaluate the Long-Term Safety and Tolerability of Intravitreal Injections of FHTR2163 in Patients with Geographic Atrophy (GA) Secondary to Age-Related Macular Degeneration (AMD)

Status: Closed To Enrollment

DERBY

A Phase III, Multi-Center, Randomized, Double-Masked, Sham-Controlled Study to Compare the Efficacy and Safety of Intravitreal APL-2 Therapy with Sham Injections in Patients with Geographic Atrophy (GA) Secondary To Age-Related Macular Degeneration (AMD)

Status: Closed To Enrollment

GX 29455

A Phase II Sham Injection-Controlled Exposure-Response Study of Lampalizumab Intravitreal Injections Administered Every Two Weeks Or Every Four Weeks for Geographic Atrophy

Status: Closed

OLEI GX28198

A Phase III Multicenter, Open-Label Extension Study to Evaluate the Long-Term Safety and Tolerability of Lampalizumab (FCFD4514S) in Patients with Geographic Atrophy Who Have Completed Genentech-Sponsored Lampalizumab Studies

Status: Closed

### **Diabetic Retinopathy Clinical Trials**

#### **PAVILION**

A Phase III, Multicenter, Randomized Study of the Efficacy, Safety, and Pharmacokinetics of the Port Delivery System with Diabetic Retinopathy

Status: Open For Enrollment

#### **PANORAMA**

A Phase III, Double-Masked, Randomized Study of the Efficacy and Safety of Intravitreal Aflibercept Injection in Patients with Moderately Severe to Severe Nonproliferative Diabetic Retinopathy

Status: Closed

### **Diabetic Macular Edema (DME) Clinical Trials**

#### **PAGODA**

A Phase III, Multicenter, Randomized, Visual Assessor-Masked, Active-Comparator Study of the Efficacy, Safety, and Pharmacokinetics of the Port Delivery System with Ranibizumab in Patients with Diabetic Macular Edema

Status: Open For Enrollment

#### **PHOTON**

A Randomized, Double-Masked Active-Controlled Phase 2/3 Study of the Efficacy and Safety of High-Dose Aflibercept in Patients with Diabetic Macular Edema

Status: Open For Enrollment

#### **RHONE X**

A Multicenter, Open-Label Extension Study to Evaluate the Long Term Safety and Tolerability of Faricimab in Patients with Diabetic Macular Edema

Status: Closed To Enrollment

#### **RHINE**

A Phase III, Multicenter, Randomized, Double-Masked Active Comparator-Controlled Study to Evaluate the Efficacy and Safety of RO6867461 in Patients with Diabetic Macular Edema

Status: Closed To Enrollment

## **Retinal Vein Occlusion (BRVO/CRVO)**

### **BALATON**

A Phase III, Multicenter, Randomized, Double-Masked, Active Comparator-Controlled Study to Evaluate the Efficacy and Safety of Faricimab in Patients with Macular Edema Secondary to Branch Retinal Vein Occlusion

Status: Enrollment Opening Soon

### **COMINO**

A Phase III, Multicenter, Randomized, Double-Masked, Active Comparator-Controlled Study to Evaluate the Efficacy and Safety of Faricimab in Patients with Macular Edema Secondary to Central Retinal or Hemiretinal Vein Occlusion

Status: Enrollment Opening Soon