Why are clinical research studies important?

Clinical research studies are scientific evaluations in people, led by researchers and physicians. They play an important part in ongoing efforts to improve healthcare. They can help us to understand a disease better, learn how best to treat it, and can lead to new treatments being made available.

There are many different reasons and benefits to participating in clinical studies. While some like to try a new approach to therapy they would typically not have access to, others like the fact that there is potential to help others with the same condition.

Are clinical research studies right for me?

Taking part in clinical research requires careful thought. Before you decide whether to participate, make sure that you understand any potential risks involved; these will be explained to you by the study doctor.

There is no guarantee that you will benefit from taking part in this study and you should never feel you have to participate in clinical research. You have the right to withdraw from the study at any time and for any reason. You will retain the right to the same standard of care you previously received.

Want to know more about the PANORAMA Study?

If you would like to learn more, please contact us at:

Clinic name: _____

Contact person: _____

Address: _____

_____

Phone No.: _____

Contacting us does not mean you will be eligible to join, or are required to join, the study.

We can tell you more about the study and talk through the potential benefits and risks of being involved before you make your decision about participating.

We look forward to hearing from you.

PANORAMA

220365 USA Recruitment 20160227 Patient Brochure English 1.0 US-EYE-1371(1)

Welcome to the PANORAMA Study

A clinical research study opportunity for people with nonproliferative diabetic retinopathy

PANORAMA

What is nonproliferative diabetic retinopathy?

Nonproliferative diabetic retinopathy (NPDR) is the earliest stage of an eye condition called diabetic retinopathy, which can lead to complications in people with diabetes that can lead to blindness.

In this eye condition the blood vessels at the back of the eye (retina) become damaged. It is often progressive, which means that it gets worse over time. As it gets worse, there is a higher risk of complications that would make it difficult to see properly.

People with NPDR may not be experiencing any problems with their vision yet, but can go on to develop symptoms.

What is the PANORAMA Study?

The PANORAMA Study will assess whether a medicine called aflibercept can improve nonproliferative diabetic retinopathy and prevent the condition from worsening. Aflibercept is "being investigated"* for this usage. The safety and efficacy of aflibercept in nonproliferative diabetic retinopathy in the absence of macular edema has not been evaluated by the U.S. FDA.

The study will include about 360 people at about 70 research centers in the United States.

How long does the study last?

Participation in the PANORAMA Study may last up to 2 years. In the first year you will visit the study clinic 11 times for a safety check and to receive your study medication. In the second year you will visit the study clinic 7 times for a safety check and to receive your study medication.

**"Being investigated" means that the medication is not FDA-approved for use to treat nonproliferative diabetic retinopathy outside of a clinical research study.*

Who can join the PANORAMA Study?

To join this study you must:

- Be at least 18 years old
- Have type 1 or type 2 diabetes mellitus
- Be confirmed to have moderately severe to severe nonproliferative diabetic retinopathy

There are other criteria that you will need to meet to join the study. The study team will assess and discuss these with you.

Joining the study is voluntary and you can leave at any time.

What will happen during the PANORAMA Study?

If you decide to join the study, we will invite you to attend a screening visit to determine whether you are right for the study, and the study is right for you.

If you qualify for the study and wish to join, you will be randomly assigned to one of three groups. Two groups will receive injections of the investigational medication and one group will receive fake (sham) injections. It will not be possible for you to choose which treatment you will receive. Neither you nor the study doctor will know which group you belong to. However, if it is medically necessary to find out, the study doctor can do so quickly.

How will I receive the study medication?

The study medication will be injected into your eye by a qualified doctor. Before the injection you will have a local anesthetic so your eye is temporarily numb. Just one eye will be given the study medication during the study.

If you are in the group who will receive a fake (sham) injection, a syringe will be used, but no needle will be attached. You will not be able to tell if you got an actual injection or not because of the numbing medicine that you will receive first.

The fake injections are important so that everyone on the study appears to get the same number of injections. This helps keep the results of the study more accurate.

You will have regular eye checks and examinations on both eyes during the study. If your vision in either eye gets worse you will be able to have appropriate treatment and still remain on the study.

Your study doctor and the study team will be able to advise you and answer any questions you may have.

There will be no charge for any study-related care or treatment provided during the study.