ForPatients
by Roche

Central Retinal Vein OcclusionNeovascular Age-related Macular DegenerationRetinal Vein OcclusionWet Age-Related Macular DegenerationBranch Retinal Vein OcclusionHemiretinal Vein OcclusionDiabetic Macular Edema

A clinical study to understand how well certain Roche ophthalmology products work over time in people with age-related macular degeneration (nAMD or wet-AMD) and diabetic macular oedema

A Real-World Study to Gain Clinical Insights Into Roche Ophthalmology Products

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	29 Countries	NCT05476926 MR41927

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

Real-World, Long-Term Data Collection to Gain Clinical Insights Into Roche Ophthalmology Products (VOYAGER STUDY)

Trial Summary:

The VOYAGER study is a primary data collection, non-interventional, prospective, multinational, multicenter study. It is designed to collect real-world, long-term data to explore long-term effectiveness, safety, clinical insights, treatment patterns, and factors driving the treatment decisions among patients being treated with specified Roche ophthalmology products in approved retinal indications (Faricimab for neovascular age-related macular degeneration [nAMD], diabetic macular edema [DME], and retinal vein occlusion; Port Delivery System with Ranibizumab for nAMD) in routine clinical practice. This study will not provide or make recommendations on use of any products including Roche products; treatment decisions will be determined by the treating physician and must be made independently to the decision to participate in this study. Participation in this study will not change or influence a patient's standard of care in any way.

Hoffmann-La Roche	N/A
Sponsor	Phase

NCT05476926 MR41927
Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
All	#18 Years	No

Why is the VOYAGER clinical study needed?

Conditions that affect the back of the eye (also called ‘retinal conditions’) are major causes of sight problems and blindness worldwide. Many medicines are available to treat retinal conditions, but more information is needed about how well these medicines work once a doctor prescribes them in routine medical practice.

Researchers hope that the information collected in this study will help doctors select the best treatment for people with specific retinal conditions.

How does the VOYAGER clinical study work?

This clinical study is recruiting people who have a retinal condition called neovascular age-related macular degeneration (nAMD or wet- AMD) or diabetic macular oedema (DMO, which is shortened to DME in the United States of America). People can take part if they have been treated or are about to start a treatment for their retinal condition with medicines that are made by Roche and that are already approved by regulatory authorities.

The purpose of this clinical study is to collect information from participants’ medical files about when and how doctors prescribe medicines and how well the medicines work.

Participants will be given treatment for their retinal condition by their doctor according to the usual standard of care. Information on the participants’ overall health and sight will be collected at their usual doctor visits, and no additional tests or appointments are required. Other information will be collected from the participant’s medical records. Participants’ data will be collected until the end of study even if they switch from using a Roche ophthalmology product or generally stop eye(s) treatment.

Participants’ total time in the clinical study will be up to 5 years, depending on when they join the study. Participants are free to leave the clinical study at any time.

What are the main endpoints of the VOYAGER clinical study?

The main clinical study endpoints (the main results that are measured in the study to see how well the medicine has worked) are changes in eyesight from the start of the study to 1 year and the type and seriousness of any side effects that may occur.

The other clinical study endpoints are changes in eyesight from the start of the study to other time points, and to describe ‘treatment patterns’. These include: which medicines

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doctors are prescribing and if for one or both eyes, how often medicines are given, and how often the doctor sees the participant for their retinal condition.

Who can take part in this clinical study?

People can take part in this study if they are adults and have been diagnosed with retinal conditions called nAMD (which is also called wet-AMD) or DMO (which is called DME in the United States of America). People must be taking or are going to take a medicine made by Roche for their retinal condition and agree to have information from their medical records used by signing an 'Informed Consent Form'. People with other retinal conditions may also be recruited if Roche medicines are approved for other retinal conditions during the study.

People cannot take part in this study if they do not agree to sign an ‘Informed Consent Form’, which allows the researchers to gather information from their medical records.

What treatment will participants be given in this clinical study?

This is a ‘non-interventional’ study, which means that there is no experimental treatment being tested. All of the medicines that are being looked at in this study have been approved by regulatory authorities for the treatment of certain retinal conditions and have been prescribed as part of the participants’ routine medical care.

Are there any risks or benefits in taking part in this clinical study?

Potential participants will be told about any risks and benefits of taking part in the clinical study. These will all be described in an informed consent document (a document that provides people with the information they need to make a decision to volunteer for a clinical study). A potential participant should also discuss these with their usual healthcare provider and with members of the research team. Anyone interested in taking part in a clinical study should know as much as possible about the study and feel comfortable asking the research team any questions about the study.

Risks associated with the clinical study

Since the study is non-interventional, it will not change how a participant’s retinal condition is managed by their doctor. There are no physical risks associated with taking part in this study. There is a small risk of loss of confidentiality of information; however, all reasonable steps will be taken to protect the identity of participants.

Potential benefits associated with the clinical study

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Participants' health will not be affected by participation in the clinical study, but the information that is collected may help other people who have a similar medical condition in the future. The information gained from this study may help researchers and doctors learn more about the long-term effect and safety of Roche ophthalmology treatments that are approved for retinal conditions.

For more information about this clinical study see the **For Expert** tab on the specific ForPatients page or follow this link to ClinicalTrials.gov.

Inclusion Criteria:

- Have provided informed consent, as required per local regulations 2.a) Adult patient, as defined by local regulations and local product label, who is newly initiating treatment (or initiated treatment in the previous visit) with a specified approved Roche ophthalmology product in retinal indication of interest for this study in at least one eye, according to the investigator's discretion in routine clinical practice; OR 2.b) Adult patient, as defined by local regulations and local product label, who is continuing treatment with any specified approved Roche ophthalmology product in retinal indication of interest for this study in at least one eye after initiating that treatment in a Roche interventional trial.

Exclusion Criteria:

- Concomitant participation of the patient in an investigational ophthalmology clinical trial that includes receipt of any investigational drug or procedure within the last 28 days prior to enrollment (this restriction does not apply to patients who are rolling over from Roche interventional studies and continuing treatment with any specified approved Roche ophthalmology product in retinal indication of interest for this study)

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