



## What is the purpose of the Elevatum study?

DME is the leading cause of vision loss in patients with diabetes. Certain populations have been historically underrepresented in clinical trials, including DME trials.



**Thank you  
for considering the  
Elevatum study.**

Clinical trials are a type of research using human volunteers to collect data and information intended to add to medical knowledge.

Your participation is greatly appreciated. You may or may not benefit directly from being in the study, but information learned may help other underrepresented adults with the same condition in the future. As with all medicines, there is a chance for side effects. You will be closely monitored for safety throughout the entire study.

The study team will happily answer any questions you may have. Remember, participation is voluntary. If you choose to leave the study, the care you receive will not be affected. Please ask your study doctor for more information.

[Elevatumexplained.com](https://www.elevatumexplained.com)

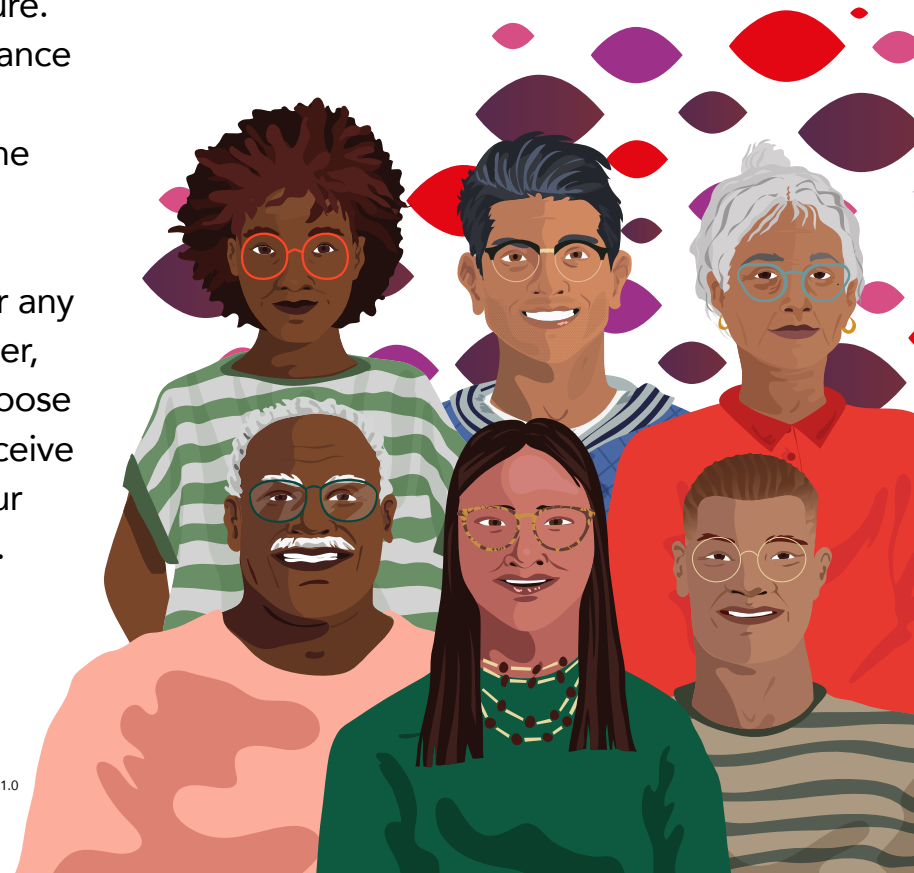
ML43435 - Elevatum Study - Study Multifold - 15 - Apr - 2022 - English (Master) - V1.0



**Genentech**  
A Member of the Roche Group

## Understanding The ELEVATUM Study

A clinical trial for people with diabetic macular edema (DME) underrepresented in research studies



## WHO IS THE STUDY FOR?

This study for adults 18 years and older who:

- Self-identify as Black/African American, Hispanic/Latino American, or Native American/Alaska Native/Native Hawaiian or other Pacific Islander.
- Have not received prior treatment in the study eye.
- Are diagnosed with diabetes mellitus (type 1 or type 2) that is being treated with medication.
- Have hemoglobin A1C (HbA1C)  $\leq 10\%$ .
  - Subset of patients can have HbA1c 10%-12%.
- Are diagnosed with diabetic macular edema (DME).

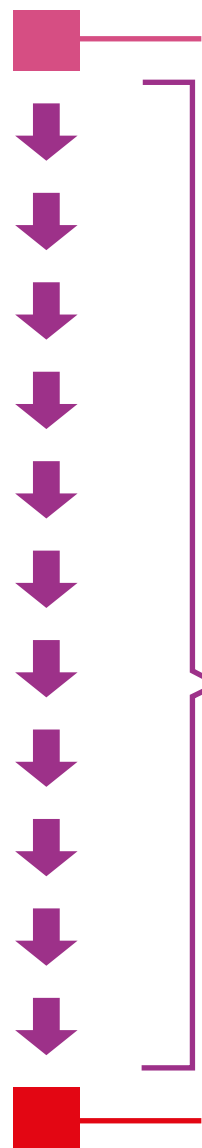
Underrepresented populations in DME clinical trials include those who self-identify as Black/African American, Hispanic/Latino American, or Native American/Alaska Native/Native Hawaiian or other Pacific Islander.

Population diversity in clinical trials is important to make sure we know how study treatments work for people of all different backgrounds. The purpose of the **Elevatum study** is to expand understanding of how faricimab, an FDA-approved medicine for DME, can help adults from underrepresented populations with DME who have not received treatment.



# WHAT HAPPENS DURING THE STUDY?

You will be in the study for a little over one year. During the study you will have 13 site visits.



## 1. SCREENING

- You will review and sign the Informed Consent Form. The Informed Consent Form contains all the information about the study. Make sure you understand the study and ask any questions you may have. If you agree to join, you will give your permission by signing this form. You will also have tests and health checks to see if the study is right for you.
- At least 1 visit, up to 4 weeks before starting treatment.

## 2. TREATMENT

- If the study is right for you, you will start treatment and have health checks and tests according to the schedule. The study is "open-label," meaning you and your study doctor know that you are receiving the active study drug.
- 11\* visits over 52 weeks.

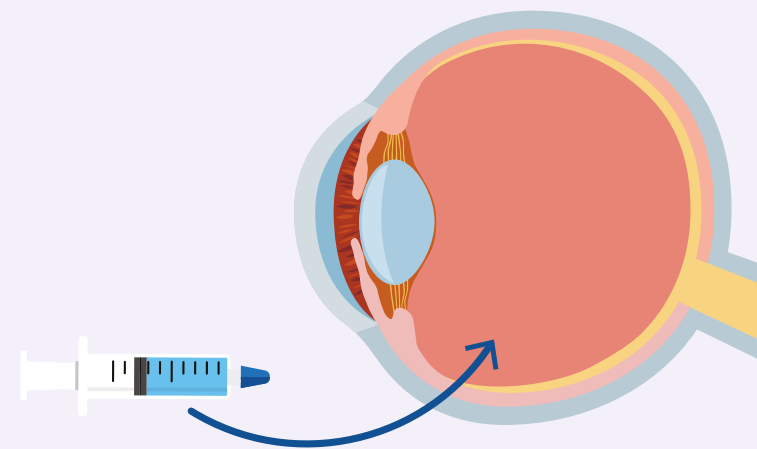
## 3. SAFETY FOLLOW-UP

- There is one final visit to check on you after you are done taking the study medicine.
- 1 visit, 4 weeks after final treatment.

\*Treatment is not administered at the Week 48 visit.

# WHAT IS THE TREATMENT?

The drug being studied is called **faricimab**, which is FDA-approved for DME. Faricimab targets and inhibits two disease pathways linked to DME by blocking angiopoietin-2 (Ang-2) and vascular endothelial growth factor-A (VEGF-A). It is delivered as an intravitreal injection, meaning as a shot into the eye. Every participant enrolled in the study will receive faricimab and will have one eye assigned as their study eye. Participants will receive up to 10 injections of faricimab.



# WHAT KIND OF EYE TESTS ARE INCLUDED IN THE STUDY?

Several different eye tests will be performed throughout the study to examine your eyes.



Vision Tests



Eye Pressure



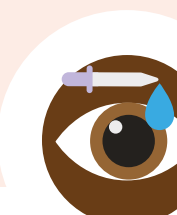
Eye Exam



Eye Imaging

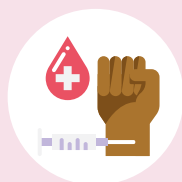


Eye Fluid Collection



For some tests, the study doctor will give you eye drops to widen the pupil (called dilation). You should not drive or use machinery until this has resolved.

# WHAT OTHER KINDS OF TESTS WILL I HAVE?\*



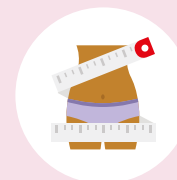
Blood tests



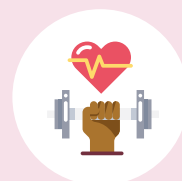
Height



Weight



Waist and hip measurement



Physical exam



Vital signs



Urine test

\*Not inclusive of all tests.



If you are interested in learning more about the Elevatum study,

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**Elevatumexplained.com**  
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