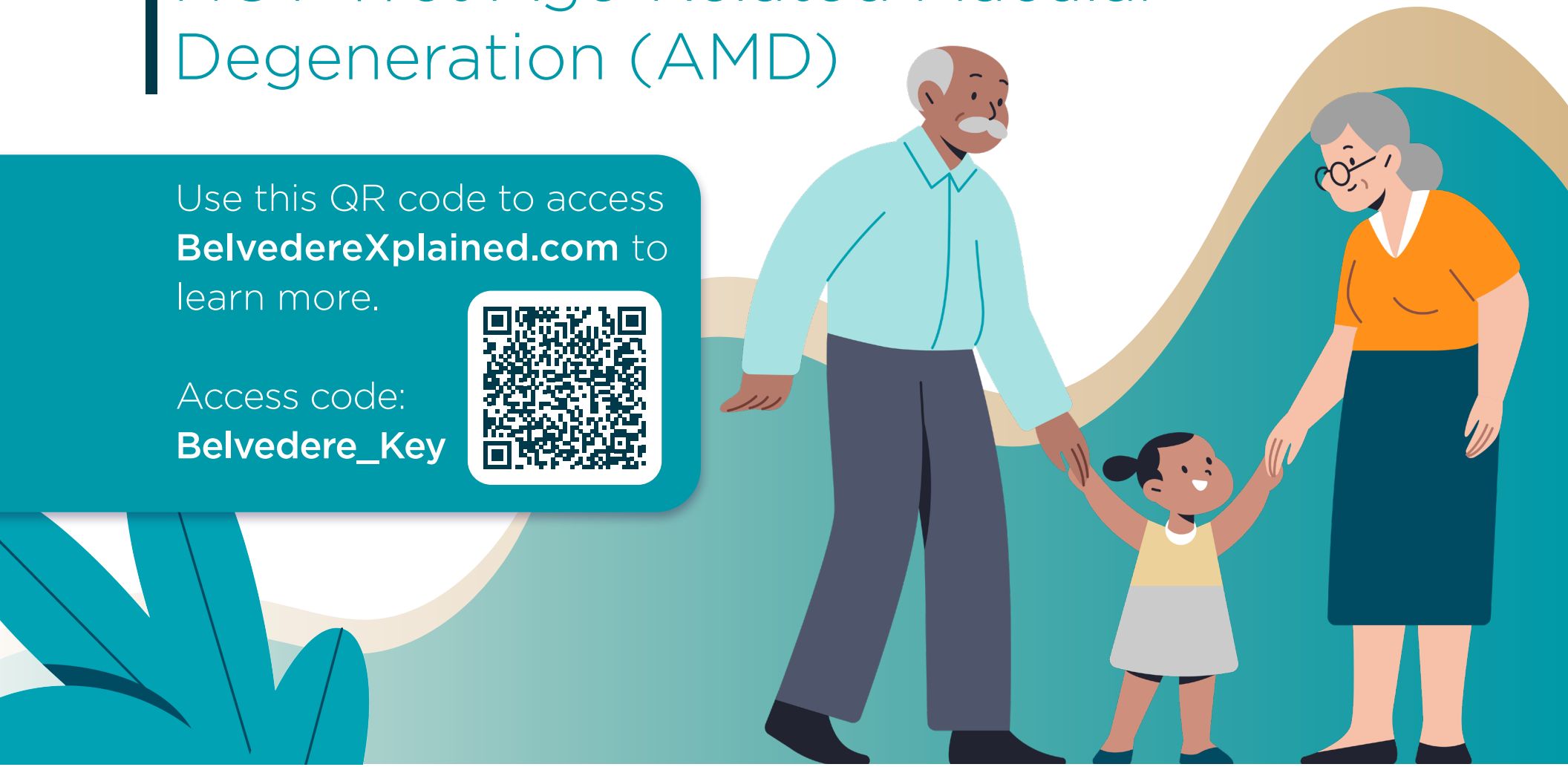
YOUR FUTURE SHOULD BE FOCUSED ON CREATING MEMORIES

NOT Wet Age-Related Macular Degeneration (AMD)

Use this QR code to access **BelvedereXplained.com** to learn more.

Access code:
Belvedere_Key



Belvedere

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Genentech
A Member of the Roche Group

WHAT IS WET AMD?

Age-Related Macular Degeneration (also known as AMD) is a chronic eye condition that can cause problems in your central vision as it progresses. It is a condition related to aging and has multiple enviromental and genetic risk factors. The **neovascular** or "**wet**" type of AMD is when abnormal blood vessels have grown and leaked fluid into the retina, causing "wet" damage there.

The growth of these blood vessels can scar the retina, potentially creating permanent blind spots in your central vision.

Wet AMD can progress over time and cause your vision to get worse without treatment.

AMD is a leading cause of vision loss in the U.S.[1]

WHAT ARE THE SYMPTOMS OF WET AMD?

Symptoms of wet AMD may occur in one or both eyes and may include:

- blurry spots, blank spots, or dark spots in your vision
- visual distortions, such as straight lines appearing wavy
- reduced central vision
- difficulty reading or seeing well at night

In some cases, patients may have wet AMD but may not notice symptoms, and the diagnosis of wet AMD is made only by eye exams.

WHAT CAUSES WET AMD?

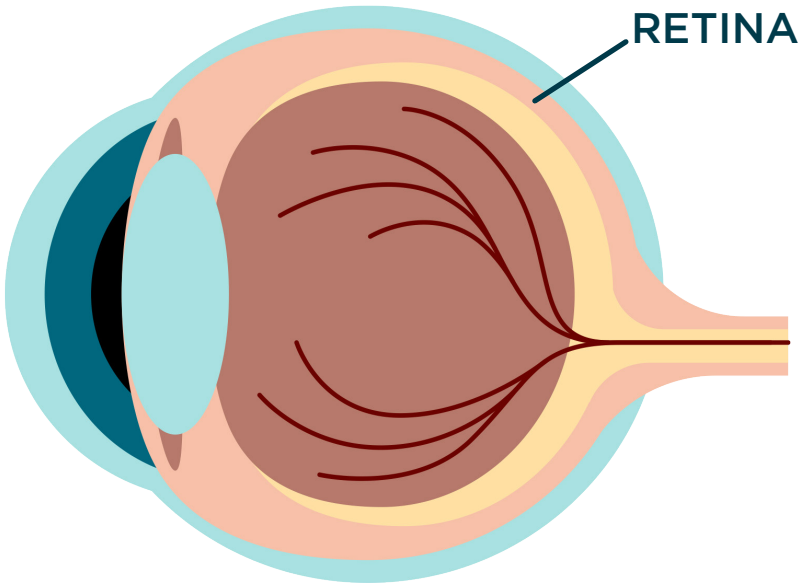
Certain risk factors such as age, environmental, and genetic risk factors make developing this disease more likely. A specific protein called vascular endothelial growth factor (VEGF) is involved in the formation and leakiness of abnormal blood vessels in wet AMD.

HOW IS WET AMD TREATED?

Currently, wet AMD is treated with a therapy that targets the VEGF protein and stops it from working. This type of therapy is called "anti-VEGF." Anti-VEGF therapy slows the growth of the leaky blood vessels in the back of your eye, and is given as an eye injection (shot) through the sclera (the white part of your eye).

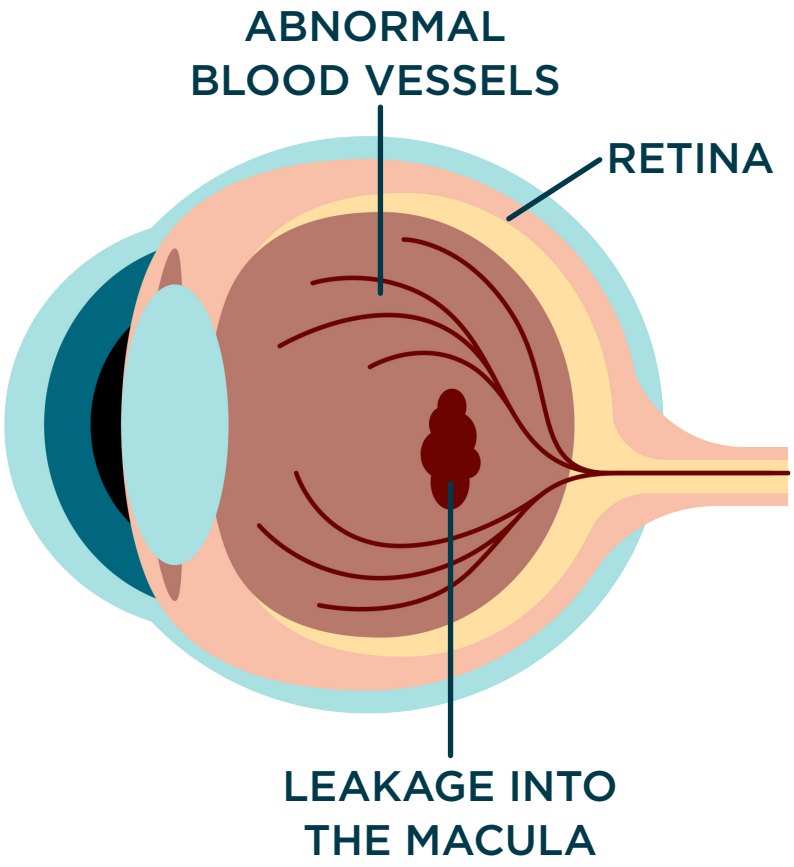
HEALTHY EYE

The ‘retina’ is the light sensitive layer at the back of the eye that takes in light from the world to allow our brain to form the images we see. The ‘macula’ is in the center of the retina and is responsible for our sharp, detailed central vision.



EYE WITH WET AMD

Abnormal blood vessels that can leak in the macula.



WHAT IS A CLINICAL TRIAL?

Clinical trials are research studies that explore whether a potential new or known treatment is safe and effective for humans. They are designed to help us find:

- Potential new treatments
- New versions of treatments already being used
- New uses for already-approved treatments

It's important to note that participant safety is the top priority of every trial. In fact, there are special groups (called Institutional Review Boards) that ensure that strict rules meant to protect the safety and privacy of trial volunteers are followed.

All known risks and benefits are outlined in a clinical trial's informed consent form, which participants must read and sign before they take part.

ABOUT THE BELVEDERE CLINICAL TRIAL

Consider taking part in Belvedere – a clinical trial that is studying a potentially new way to deliver wet AMD study treatment to see if it could result in fewer eye injections and eye doctor visits. The Belvedere trial is studying a drug delivery system called SUSVIMO that is designed to continuously deliver a special form of an anti-VEGF therapy (ranibizumab) from a small, refillable implant that is surgically inserted into the eye of patients with wet AMD who have had anti-VEGF eye injections other than ranibizumab in the past.

This brochure will tell you a bit more about the Belvedere trial to help you decide if you would like to take part.

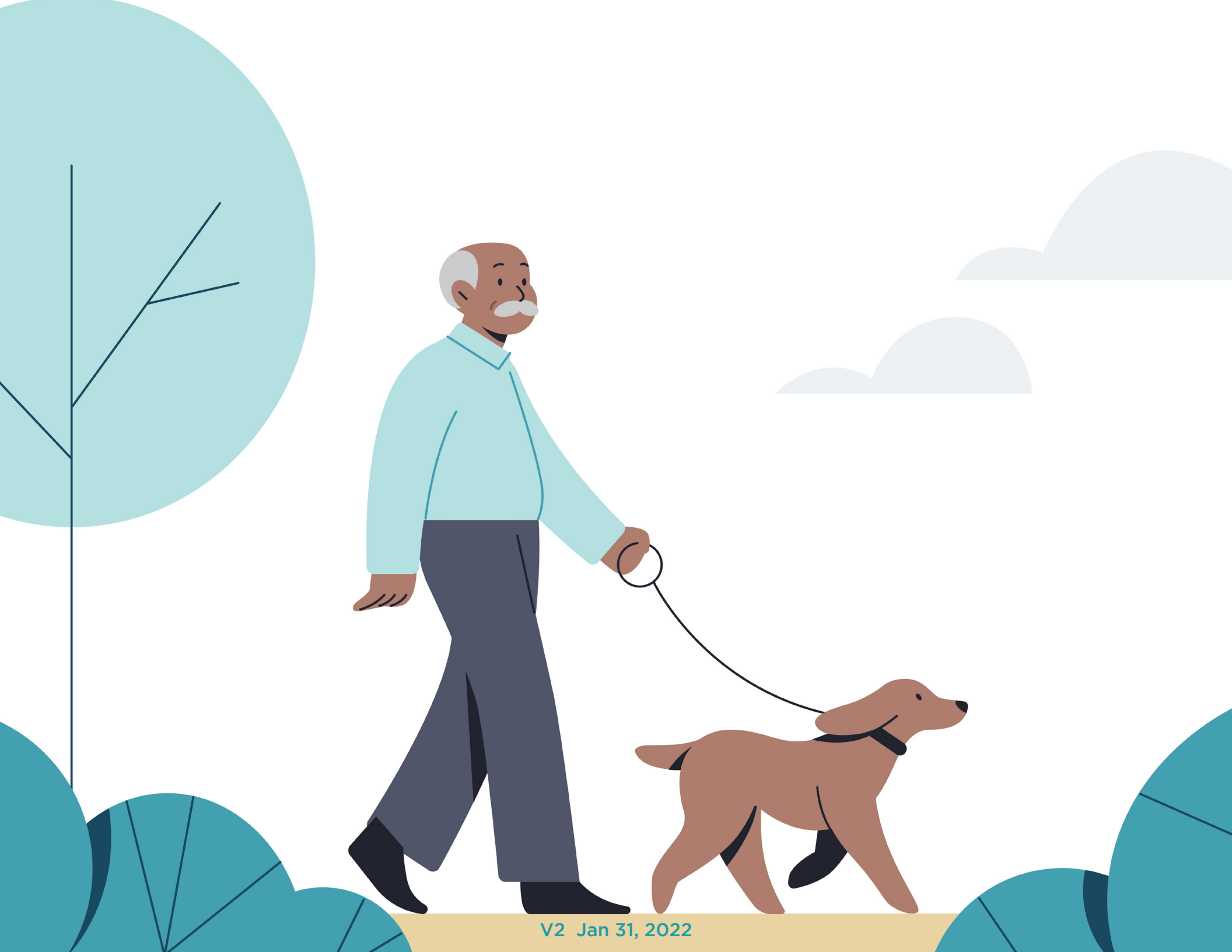
Ranibizumab is a drug that blocks VEGF, therefore slowing the growth of and leakage from damaged blood vessels in your eye. Ranibizumab is approved to be delivered through regular monthly eye injections and through an ocular implant for certain patients with wet AMD.

A special form of ranibizumab just means a 'different formula'. In Belvedere, it means we are studying a drug delivery system that has the same active ingredient as ranibizumab.

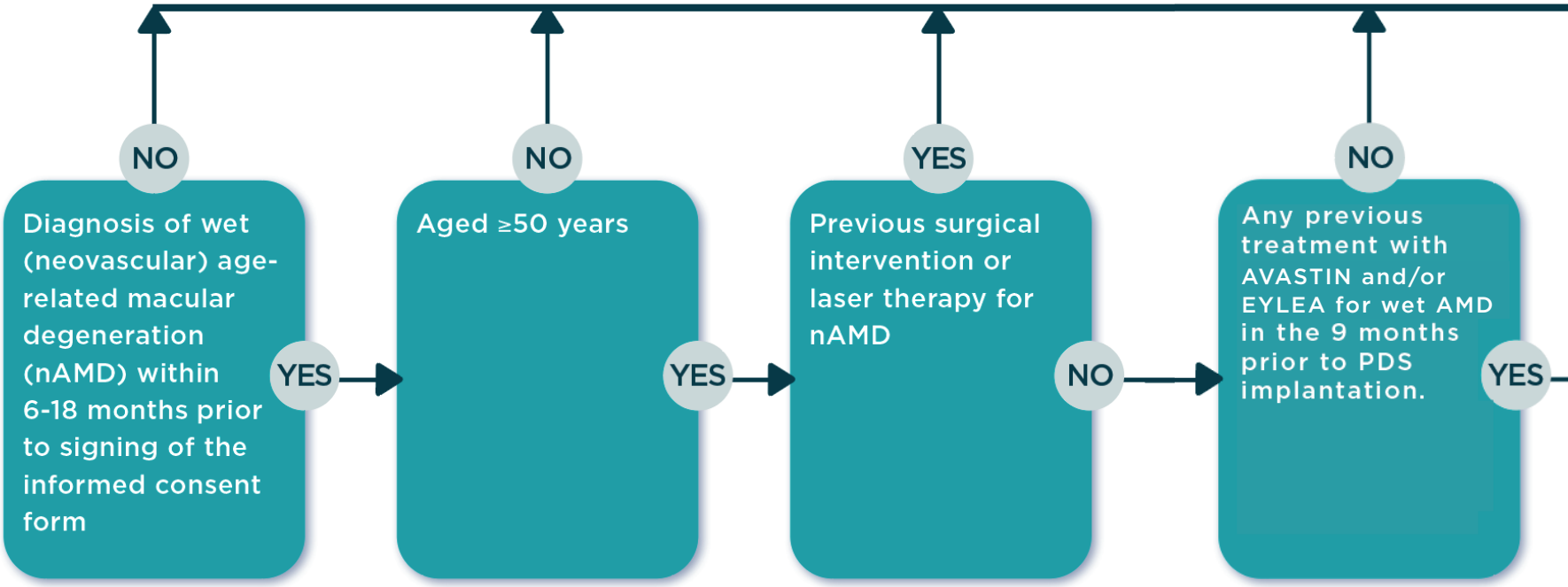
WHO CAN TAKE PART?

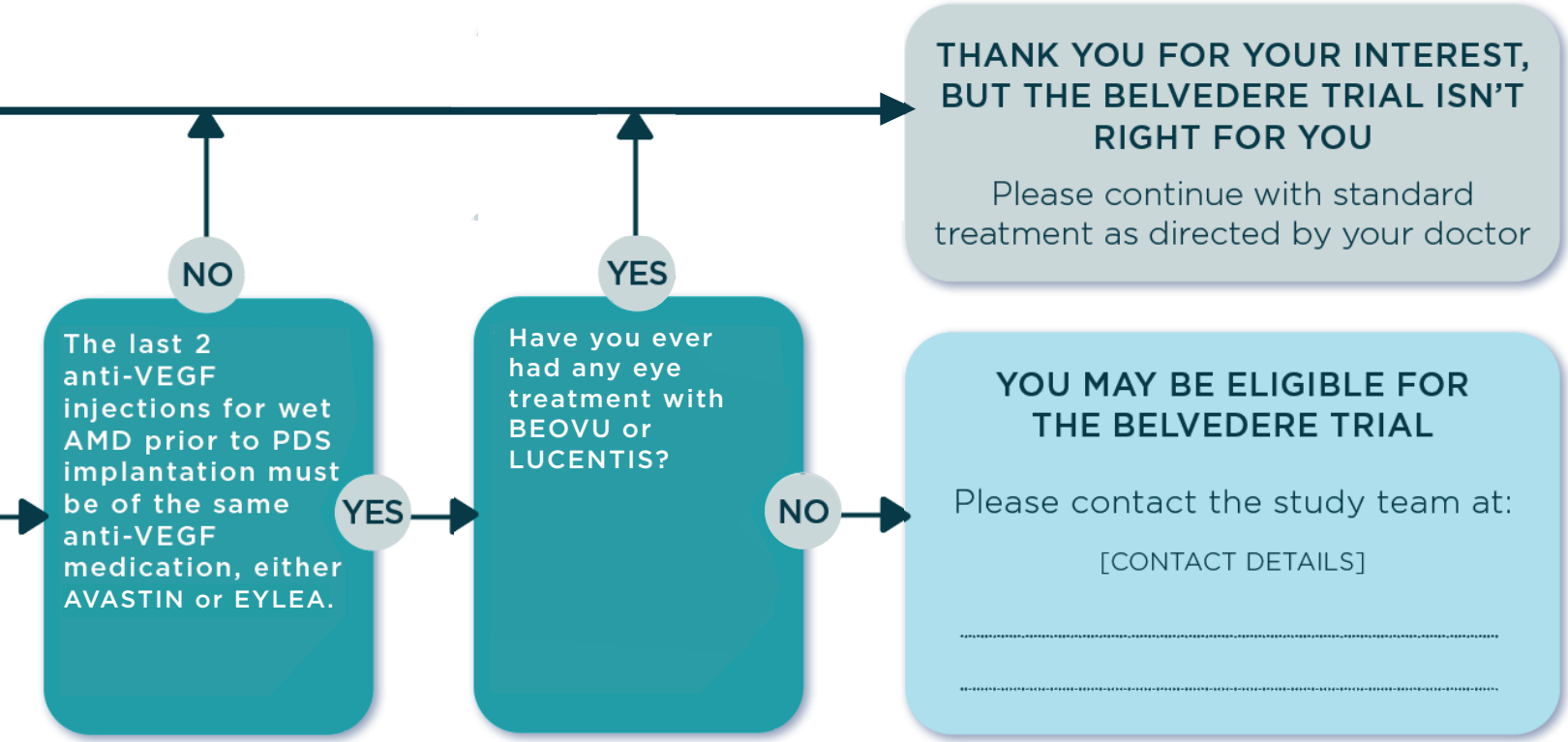
WE ARE LOOKING FOR ABOUT 200 PEOPLE TO TAKE PART WHO (AMONG OTHER THINGS):

- Are at least 50 years old
- Have been diagnosed with wet (neovascular) AMD in the last 6-18 months
- Have had at least 3 past eye injections of anti-VEGF medication other than ranibizumab in the last 9 months



AM I ELIGIBLE FOR THE BELVEDERE CLINICAL TRIAL?




NO
YES
The last 2 anti-VEGF injections for wet AMD prior to PDS implantation must be of the same anti-VEGF medication, either AVASTIN or EYLEA.
YES
Have you ever had any eye treatment with BEOVU or LUCENTIS?
NO
THANK YOU FOR YOUR INTEREST, BUT THE BELVEDERE TRIAL ISN'T RIGHT FOR YOU
Please continue with standard treatment as directed by your doctor
YOU MAY BE ELIGIBLE FOR THE BELVEDERE TRIAL
Please contact the study team at:
[CONTACT DETAILS]

WHAT DOES TAKING PART IN BELVEDERE INVOLVE?

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Total time in study: 1 year

SCREENING PHASE

We will assess your suitability to take part.

Please note that only one eye will be chosen as the 'study eye'.

TRIAL DESIGN

Everyone in the trial will have the eye implant surgically inserted containing the special form of ranibizumab, with refills of the implant with ranibizumab at month 6 and month 12.

The day of surgery to place the PDS implant will be Day 1. Following that, visits will occur at day 2, week 1, week 4, and then every 4 weeks until the end of the trial (week 52) via a mix of in-person clinic visits and telemedicine visits.

If the concentration of the drug delivered by the implant is not sufficient to control the wet AMD disease activity in your study eye such that certain criteria are met in terms of your vision test and retinal scanning result at certain study visits, your study doctor may give you an eye injection of ranibizumab.

After injections, you will continue to receive the same doses of the special form of ranibizumab as refill-exchanges into your eye implant.

WHAT HAPPENS AT TRIAL VISITS?

IN-PERSON VISITS:

After the initial implant surgery, you'll be seen in clinic on day 2, week 1, month 1, month 2 then every 8 weeks until the end of your time in the trial (week 52). There will be approximately 10 in-person clinic visits in this study and visits may last 2 to 4 hours. As is common in trials, transportation to and back from office visits can be provided at no cost to you.

TELEMEDICINE VISITS:

In between your in-person clinic visits, you will participate in approximately 5 study assessments by telephone or video call, which are referred to as telemedicine visits. These are scheduled in between your every 8 week in-person clinic visits. With the help of your support system, you may be asked to take a photo of your study eye.

In summary, there is a mix of in-person and telemedicine visits every 4 weeks after the first week of your implant surgery until the end of the trial at week 52.

Health assessments will vary between visits, but may include:

Vision test

Eye scans

Questionnaires

FREQUENTLY ASKED QUESTIONS

HOW IS THE IMPLANT INSERTED INTO THE EYE?

You will have the implant surgically inserted into the study eye at the beginning of the trial.

The surgical study procedure is typically less than 30 minutes. Your eye will be anesthetized (numbed) with a medication prior to the procedure so you will not feel any pain during the procedure.

DO THE REFILLS HURT?

The refills are administered to the study device implanted in the eye. Due to this, the needle pierces the conjunctiva and then enters the implant. Numbing drops are used prior to doing the refill-exchange procedure. Participants in past and ongoing trials have anecdotally told us that they feel some pressure around the eye, but they do not feel pain.

DO EYE INJECTIONS HURT?

The supplemental treatment with an eye injection of ranibizumab is administered in the same way as other intravitreal injections you may have received for your wet AMD. However, we will numb your eye with a medication prior to the injection so you will not feel any pain during the procedure.

DO I HAVE TO PAY TO TAKE PART?

While participating in this study, you will not have to pay for study drug or study procedures that are required only for this study and are not part of your regular medical care.

ONCE I JOIN A TRIAL, CAN I CHANGE MY MIND?

Participation is voluntary and you can leave a trial at any time. However, in order to leave a trial safely, we ask that participants contact us so that we can schedule a final visit to check on your health before you withdraw from the trial.

WHAT ARE THE RISKS AND BENEFITS OF TAKING PART IN THIS CLINICAL TRIAL?

Your vision and other symptoms caused by your wet AMD may or may not improve in this study, but the information that is learned may help other people who have a similar medical condition in the future.

- You may have side effects from the study drugs or study procedures used in this study. They can be mild to severe and even life threatening, and they can vary from person to person.

- There may be a risk in exposing an unborn child to the study drug, and all risks are not known at this time. Women who may become pregnant must take precautions to avoid exposing an unborn child to the study drug. If you are pregnant, become pregnant, or are currently breastfeeding, you cannot take part in this study.

The risks and benefits of participation are outlined in detail in the informed consent form (ICF) that you must read and sign before you can take part. Talk to your doctor about the Belvedere clinical trial, to consider if this might be an option for you.

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Thank you for your interest in the Belvedere clinical trial

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REFERENCES

1. National Eye Institute. Health Information: Age-related Macular Degeneration. Available at: https://www.nei.nih.gov/learn-about-eye-health/resources-for-health-educators/eye-health-data-and-statistics/age-related-macular-degeneration-amd-data-and-statistics Accessed May 3rd, 2021.

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LEARN MORE

Thank you for taking the time to read this brochure. If you think you may be interested in taking part in the Belvedere clinical trial, or would like more information, please contact the trial team for a no-obligation chat.

CONTACT DETAILS

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