

# A study investigating the effectiveness, safety and quality of life in participants with age related visual impairment (macular degeneration) who have switched to faricimab, under real world conditions in Germany

<b>Submission date</b> 06/09/2023	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 07/09/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/07/2024	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English Summary

### Background and study aims

Neovascular age-related macular degeneration (nAMD) is a disease that causes damage to the light-sensitive layer at the back of the eye (retina) leading to loss of sharp fine detailed vision required for daily activities such as reading, driving, and recognizing faces. A group of medicines called anti-vascular endothelial growth factors (aVEGF) have been a great success in treating patients with nAMD. However, in the long term, real-world results seem to be declining and may vary. Faricimab is a drug for administration into the eye via a fine needle (intravitreal injection) treatment used in patients with nAMD. Faricimab is approved by the United States Food and Drug Administration and the European Commission for the treatment of nAMD. The main aim of this study is to gather knowledge by collecting long-term data on previously treated participants with nAMD and to better understand the effectiveness, safety, and influence on the quality of life of faricimab in previously treated patients with nAMD under real-world conditions.

### Who can participate?

Patients aged at least 50 years old with nAMD

### What does the study involve?

Participants will take part in this study for approximately 24 months. Participants treated with faricimab will be observed in this 24-month period and the corresponding long-term data will be collected.

Study doctors will collect information regarding the participants' age, gender, ethnicity, and relevant clinical parameters from interviews or medical examinations according to local practice. The details on faricimab therapy and reasons for changes, if applicable, will be recorded at each visit.

Additionally, the quality of life of the participants will also be assessed using a set of questionnaires called National Eye Institute Visual Function Questionnaire [NEI VFQ-25] and Short Form-36 Health Survey [SF-36] questionnaire. Participants are required to fill out these questionnaires at specified time points.

What are the possible benefits and risks of participating?

It is not intended that participants will receive any benefit from this study. The data collected might help in the better understanding of the limitations of the current therapies for nAMD, the reason for non-adherence, and the treatment patterns in a real-world setting.

There may be unknown or unforeseen risks, including privacy risks, associated with participating in this study.

Only the data available from routine clinical practice will be collected; thus, there could be some missing data.

The data to be captured for this study will be collected from the sites where diagnosis and treatment of disorders of the eye take place (ophthalmologic sites) and not from any other healthcare providers. Hence there may be an under-reporting of the data other than that related to eye and related disorders.

Where is the study run from?

Roche Pharma AG (Roche Germany)

When is the study starting and how long is it expected to run for?

November 2022 to June 2027

Who is funding the study?

Roche Pharma AG (Roche Germany)

Who is the main contact?

global.trial\_information@roche.com

## Contact information

**Type(s)**

Public

**Contact name**

Dr Clinical Trials

**Contact details**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

ML44059

## Study information

### Scientific Title

A non-interventional, multicenter study to investigate effectiveness, safety and quality of life in nAMD switch patients treated with faricimab under real world conditions in Germany

### Acronym

PASSENGER

### Study hypothesis

The aim of the study is to evaluate the effectiveness of intravitreal injection treatment of faricimab on maintaining vision in previously treated neovascular age related macular degeneration (nAMD) participants treated for the first time with faricimab under real-world conditions.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

Approved 10/01/2023, Westphalia-Lippe Ethics Commission (Ethik-Kommission Westfalen-Lippe) (Gartenstr. 210–214, Munster, 48147, Germany; +49 (0)251 929 2460; ethik-kommission@aekwl.de), ref: 2022-847-f-S

### Study design

Single-arm prospective multicenter non-interventional study

### Primary study design

Observational

### Secondary study design

Case series

### Study setting(s)

Medical and other records, Optician

### Study type(s)

Quality of life, Safety, Efficacy

### Participant information sheet

No participant information sheet available

**Condition**

Neovascular age related macular degeneration (nAMD)

**Interventions**

Participants will be observed for effectiveness, safety, and quality of life once every 4 weeks during the loading dose phase (if applicable) and thereafter according to routine clinical practice for treatment (approximately once every 8 weeks to once every 16 weeks) for 24 months. Participants will also be required to fill out certain questionnaires such as the National Eye Institute Visual Function Questionnaire [NEI VFQ-25] and Short Form-36 Health Survey [SF-36] during the study. Optical coherence tomography (OCT) images of the participants that are collected within the scope of routine clinical practice during this study, will be additionally analysed by imaging experts in three different reading centers.

**Intervention Type**

Drug

**Pharmaceutical study type(s)**

Not Applicable

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Faricimab

**Primary outcome measure**

Mean change from baseline in visual acuity measured per local practice at Week 52

**Secondary outcome measures**

1. Percentage of participants with an extended treatment interval without losing >4 letters in best-corrected visual acuity (BCVA) compared to baseline measured by Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score at Week 52 and Week 104
2. Percentage of participants with an extended treatment interval compared to baseline measured by ETDRS Letter Score at Week 52 and Week 104
3. Percentage of participants in different treatment intervals compared to baseline measured using data collected on the electronic case report form (eCRF) after 52 Weeks
4. Percentage of participants in different treatment intervals compared to baseline measured using data collected on the eCRF after 104 Weeks
5. Mean change from baseline in visual acuity assessed using ETDRS Letter Score at Week 104
6. Mean change from baseline in central subfield thickness (CST) measured by the reading center using OCT from baseline up to Week 104
7. Mean change from baseline in central point thickness (CPT), measured by the investigator using OCT from baseline up to Week 104
8. Percentage of participants with the absence of intraretinal fluid (IRF) within the ETDRS Grid measured by the investigator using OCT from baseline up to Week 104
9. Percentage of participants with the absence of subretinal fluid (SRF) within the ETDRS Grid measured by the investigator using OCT from baseline up to Week 104
10. Percentage of participants with absence of sub-retinal pigment epithelium fluid (Sub-RPE fluid) within the ETDRS grid measured by the investigator using OCT from baseline up to Week 104

11. Percentage of participants with absence of IRF and SRF within the ETDRS grid measured by the investigator using OCT from baseline up to Week 104
12. Percentage of participants with absence of IRF, SRF and Sub-RPE fluid within the ETDRS grid measured by the investigator using OCT from baseline up to Week 104
13. Percentage of participants with pigment epithelial detachment (PED) within the ETDRS grid measured by the investigator using OCT from baseline up to Week 104
14. Percentage of participants with no or with clinically insignificant fluid within the ETDRS grid measured using OCT from baseline up to Week 104
15. Regime of switch of therapy measured using data collected on the eCRFs from baseline up to Week 104
16. Number of injections after treatment initiation with faricimab measured using data collected on the eCRF from baseline up to Week 104
17. Number of faricimab injections measured using data collected on the eCRF at Weeks 52 and 104
18. Number of reasons for therapy switch to faricimab given by the participants measured using data collected on the eCRF from baseline up to Week 104
19. Percentage of participants with treatment adherence and non-adherence measured using data collected on the eCRF up to Week 52
20. Percentage of participants with treatment adherence and non-adherence measured using data collected on the eCRF up to Week 104
21. Number of reasons for treatment non-adherence given by participants measured using data collected on the eCRF up to Week 104
22. Number of reasons for therapy switch from faricimab measured using data collected on the eCRF from baseline up to Week 104
23. Number of reasons for discontinuation of faricimab measured using data collected on the eCRF from baseline up to Week 104
24. Mean change from baseline in NEI VFQ-25 measured using NEI VFQ-25 Questionnaire at Weeks 52 and 104
25. Mean change from baseline in SF-36 score measured using SF-36 Questionnaire at Weeks 52 and 104
26. Mean score of NEI VFQ-25 measured using NEI VFQ-25 Questionnaire at baseline, Weeks 52 and 104
27. Mean score of SF-36 measured using SF-36 Questionnaire at baseline, Weeks 52 and 104
28. Percentage of participants with serious adverse events (SAEs), non-serious AEs and AEs of special interest (AESIs) up to approximately 48 months

**Overall study start date**

23/11/2022

**Overall study end date**

30/06/2027

## Eligibility

**Participant inclusion criteria**

Current inclusion criteria as of 17/07/2024:

1. Signed informed consent
2. Diagnosis of nAMD
3. Is at least 50 years old
4. Previously treated with an (anti) vascular endothelial growth factor (aVEGF)-drug (at least 3

doses) but no longer than 36 months since the first aVEGF injection (study eye) with clinical features of diabetic retinopathy (e.g.: microaneurysms, hemorrhages, etc.)

5. The last injection of the previous aVEGF has to be longer than 4 weeks before the first faricimab injection

6. Active nAMD, defined as persistent IRF and/or SRF on OCT despite treatment with aVEGF therapy or participants who could benefit from treatment intervals beyond their current standard treatment

7. BCVA in the study eye between 30 and 80 letters of ETDRS at first faricimab treatment

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#### Previous inclusion criteria:

1. Signed informed consent

2. Diagnosis of nAMD

3. Is at least 50 years old

4. Previously treated with an (anti) vascular endothelial growth factor (aVEGF)-drug (at least 3 doses) but no longer than 24 months since the first aVEGF injection (study eye)

5. The last injection of the previous aVEGF has to be longer than 4 weeks before the first faricimab injection

6. Active nAMD, defined as persistent IRF and/or SRF on OCT despite treatment with aVEGF therapy or participants who could benefit from treatment intervals beyond their current standard treatment

7. BCVA in the study eye between 30 and 80 letters of ETDRS at first faricimab treatment

#### Participant type(s)

Patient

#### Age group

Mixed

#### Lower age limit

50 Years

#### Sex

Both

#### Target number of participants

620

#### Participant exclusion criteria

1. Off-label use of faricimab

2. Previously treated with photodynamic therapy and retinal laser therapy (study eye)

3. Other retinal disease/intraocular condition (e.g., diabetic retinopathy, diabetic macular oedema, myopia >-6 diopter, angioid streaks, vision-reducing cataract) that, in the opinion of the investigator, could have an influence on the visual acuity (study eye)

4. Medical history of diabetes type 1 or 2

5. Participation in any other ophthalmological interventional and/or non-interventional study

6. Previously treated with faricimab (study eye); however, the first faricimab treatment may have occurred up to 12 weeks prior to enrollment

7. Pregnant and/or breastfeeding

**Recruitment start date**

28/06/2023

**Recruitment end date**

27/06/2025

## **Locations**

**Countries of recruitment**

Germany

**Study participating centre**

**Augenabteilung am St. Franziskus-Hospital**

Munster

Germany

48145

**Study participating centre**

**Augenarztpraxis Dr.Mihaescu & Kollegen**

Würzburg

Germany

97080

**Study participating centre**

**MVZ Augenzentrum am Berliner Ring**

Würzburg

Germany

97080

**Study participating centre**

**Augentagesklinik am Spreebogen Berlin**

Berlin

Germany

10559

**Study participating centre**

**AUGENZENTRUM auf der Insel,**

Pfaffenhofen an der Ilm

Germany

85276

**Study participating centre**

**Südblick GmbH - Augenzentrum Prinz 25; Makula & Drye Eye Center**

Augsburg

Germany

86150

**Study participating centre**

**Augenärzte Hamburg Dr. Kaupke MVZ GmbH**

Hamburg

Germany

22587

**Study participating centre**

**Augenheilkunde Oberricklingen Hannover**

Germany

30459

**Study participating centre**

**St. Elisabeth Krankenhaus Köln Hohenlind Köln**

Germany

50935

**Study participating centre**

**Dietrich-Bonnhöffer-Klinikum Neubrandenburg**

Germany

17036

**Study participating centre**

**Augenzentrum Frankfurt Prof. Koch und Dr. Deuchler**

Germany

60549

**Study participating centre**

**Institut für Augenheilkunde Halle Halle**

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**Study participating centre**  
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## Sponsor information

### Organisation

Roche Pharma (Roche Germany)

### Sponsor details

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### Sponsor type

Industry

### Website

<https://www.roche.com/about/>

## Funder(s)

### Funder type

Industry

### Funder Name

Roche Pharma AG (Roche Germany)

## Results and Publications

### Publication and dissemination plan

1. Planned abstract at DOG 2024
2. Planned methodological publication in a peer-reviewed journal
3. Planned abstract at DOG 2025
4. Planned abstract at DOG 2026
5. Planned final publication in a high-impact peer-reviewed journal

### Intention to publish date

30/10/2028

### **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available due to participant-level data not being a regulatory requirement.

### **IPD sharing plan summary**

Not expected to be made available