

Description of the quality of life of patients with neovascular age-related macular degeneration initiating or switching to faricimab in the real-world setting

Submission date 13/08/2026	Recruitment status Recruiting	☒ Prospectively registered ☐ Protocol
Registration date 07/09/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 04/09/2026	Condition category Eye Diseases	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Age-related macular degeneration (AMD) is a neurodegenerative disease of the central retina which is characterized by choroidal neovascularization (CNV) and causes irreversible destruction of the macula and loss of the sharp, central vision (fine detail vision) required for important everyday activities for patients such as reading, driving, recognizing faces (Holekamp, 2019). Faricimab is a drug for intravitreal (IVT) injection used in patients with nAMD, among others, to target both VEGF and cytokine angiopoietin 2 (Ang-2).

Roche France sets up this non-interventional study (NIS) to describe the impact of faricimab and its extended treatment intervals on health-related quality of life (HRQoL), autonomy, treatment burden and economic burden for nAMD patients and their informal caregivers*, as well as to describe the effectiveness and safety of faricimab in the real-world setting. To address these objectives, two cohorts of nAMD patients – treatment-naïve (“Naïve” cohort) or previously treated with an anti-VEGF (“Switch” cohort) – who will initiate faricimab will be composed. These cohorts will allow to distinguish most appropriate criteria according to patients’ profile included in each cohort.

* i.e., Non-professional person - family member or close friend - who provides assistance to a person who has difficulty performing certain activities of daily living on their own

Who can participate?

Patients aged 18 years and over diagnosed with an unilateral nAMD in France for whom their doctor has decided to prescribe faricimab, with visual acuity ≥ 6 in the other eye.

What does the study involve?

Participants will follow their standard medical care. In addition, patients included will be asked to complete PROs questionnaires at baseline (necessarily prior to the first faricimab injection) and during the 24-month observation period at follow-up visits at around 6 months, 12 months,

18 months and 24 months of treatment (between 2 and 14 days after faricimab injection). A trained nurse from a PRO logistic call center will contact the patient for a standardized phone interview to fulfill all applicable PROs questionnaires.

What are the possible benefits and risks of participating?

As this is an observational study where patients receive standard care prescribed by their doctor, there are no additional medical risks associated with the study itself. There is no direct benefit, but participation helps improve understanding of nAMD treatment.

Where is the study run from?

Roche (France)

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

From October 2026 to April 2030

Who is funding the study?

Roche (France)

Who is the main contact?

Anne-Sophie Franquet (anne-sophie.franquet@roche.com)

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Additional identifiers

Study information

Scientific Title

FARicimab in nAMD: a French study aiming to evaluate patient's quality of life in the real world setting

Acronym

FARILIFE

Study objectives

The primary objective of this study is as follows:

To evaluate the Health Related Quality of Life of patients suffering from nAMD, initiating or switching to faricimab, after 12-months of faricimab treatment in the real-world setting

The secondary objectives of this study are as follows:

1. To describe patient and disease characteristics
2. To assess the disease burden
3. To evaluate the effectiveness of faricimab on visual acuity
4. To evaluate the effectiveness of faricimab on anatomical outcome measurements using optical coherence tomography

5. To describe faricimab treatment patterns
6. To describe the economic impact of the treatment for patients and informal caregivers

The safety objective for this study is as follows:

To evaluate the ocular and non-ocular safety of faricimab in nAMD in real conditions of use

The exploratory objectives are as follows:

1. To search for predictive factors associated with an improvement in HRQoL or disease burden
2. Identify subgroups of patients with similar trends in HRQoL or disease burden, using clustering methods

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 04/06/2026, South-East V Research Ethics Committee (Comité de protection des personnes Sud-Est V) (CHU de Grenoble Alpes CS 10217, GRENoble, 38043, France; +33(0) 0476765783; cppsudest5@chu-grenoble.fr), ref: 26-ROCH-02

Primary study design

Observational

Secondary study design

Longitudinal study

Study type(s)

Health condition(s) or problem(s) studied

Patient suffering from neovascular age-related macular degeneration.

Interventions

The FARILIFE study is a French, national, multicenter, prospective, primary data collection, non-interventional study of two cohorts of nAMD patients, treatment-naïve ("Naïve" cohort) or previously treated with an anti-VEGF ("Switch" cohort), being treated with faricimab.

In this study, 400 patients, distributed in two cohorts, will be included across approximately 30 sites in France:

"Naïve" cohort (n=200): treatment-naïve patients who were never treated for nAMD prior to the inclusion date and initiating faricimab.

"Switch" cohort (n=200): patients who were previously treated with an anti-VEGF for nAMD prior to the inclusion date and switching to faricimab.

Each patient included in the study will be followed prospectively from inclusion to the end of the 24-month study observation period or early termination of the study (withdrawal of non-opposition or refusal to continue to participate, faricimab permanent discontinuation, participation in a clinical study, loss to follow-up or death), whichever comes first. The reason for study discontinuation will be documented. Patients are free to withdraw participation at any time.

During the study, included patients will be asked to complete PRO questionnaires at baseline (necessarily prior to the first faricimab injection) and during the 24-month observation period at

follow-up visits at around 6 months, 12 months, 18 months and 24 months of treatment (between 2 and 14 days after faricimab injection). A trained nurse from a PRO logistics call center will contact the patient for a standardized phone interview to complete all applicable PRO questionnaires.

Informal caregivers will also be asked to complete a PROs questionnaire at baseline and every 6 months. Caregivers will complete the questionnaires via a website.

For treatment-naïve patients who do not have a main informal caregiver identified at baseline, the caregiver questionnaires will be completed starting at 6 months of treatment.

This study is non-interventional; the choice of treatments, including faricimab, is at the discretion of the treating physician according to the local clinical practice, and all treatment decisions will be determined independently of participation in this study. Participation in this study will not change or influence the patient's care management in any way. All patient visits will be conducted according to routine clinical practice.

Clinicians will have to complete the eCRF (electronic Case Report Form) at selection, inclusion and during the follow-up period at around 6 months, 12 months, 18 months, and 24 months. Faricimab treatment and management information should be recorded in the eCRF at each visit.

Intervention Type

Biological/Vaccine

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Faricimab

Primary outcome(s)

1. Health Related Quality of Life of patients suffering from nAMD, initiating or switching to faricimab, after 12 months of faricimab treatment in the real-world setting measured using , for the "Naïve" cohort: Change from baseline in NEI-VFQ-25 composite score (% of patients with stable or improved score: Yes/No) - For the "Switch" cohort: Change from baseline in Treatment Burden Score (TBS) (% of patients with stable or improved TBS: Yes/No) at baseline, 6, 12, 18 and 24 months

Key secondary outcome(s)

1. Patient and disease characteristics (Socio-demographic characteristics ; Medical history: Comorbidities of interest and ocular concomitant medications and interventions; nAMD disease history; nAMD prior treatment history; informal caregiver socio-demographic characteristics) measured using patient interview at baseline

2. The disease burden measured using 2.1. Treatment burden ("Naïve" cohort): Change in TBS; 2.2. Quality of Life ("Switch" cohort): Change in NEI-VFQ-25; 2.3. Autonomy: Change in IADL score; 2.4. Burden on informal caregivers: Change in CRA score at baseline, 6, 12, 18 and 24 months

3. Effectiveness of faricimab on visual acuity measured using BCVA at baseline, 6, 12, 18 and 24 months

4. Effectiveness of faricimab on anatomical outcome measurements (OCT) measured using Number and percentage of patients with presence/absence of IntraRetinal Fluid ; Number and percentage of patients with presence/absence of SubRetinal Fluid; Number and percentage of patients with presence/absence of IntraRetinal Fluid and SubRetinal Fluid at baseline, 6, 12, 18 and 24 months

5. Faricimab treatment patterns measured using 5.1 Number of injections over time and during the loading dose phase; 5.2 Time interval between injections; 5.3 Number and percentage of patients according to faricimab treatment interval; 5.4 Number and percentage of patients according to faricimab treatment regimen (T&E, PRN, Observe and Plan, Fixed dosing, Other); 5.5 Total number, number and percentage of visits with or without faricimab injection; 5.6 Number and percentage of missed or delayed visits (with or without injection); 5.7 Number and percentage of treatment adherence (defined as patient keeps/attends the visit appointment scheduled with the investigator) and non-adherence; 5.8 Reasons for treatment non-adherence in terms of number and percentages; 5.9 Number and percentage of patients with permanent treatment discontinuation with or without switch, and reasons; 5.10 Number, type, and frequency of ocular concomitant and subsequent medications and interventions received during the study period at baseline, 6, 12, 18 and 24 months

6. Economic impact of the treatment for patients and informal caregivers measured using economic patient questionnaire and the economic caregiver questionnaire at baseline, 12 and 24 months

Completion date

15/04/2030

Eligibility

Key inclusion criteria

1. Age ≥ 18 years old
2. Diagnosis of unilateral* nAMD (study eye)
3. Treatment-naïve ("Naïve" cohort) or previously treated with at least 3 doses of an anti-VEGF ("Switch" cohort) (study eye)
4. For whom treatment with faricimab is to be initiated
5. VA score ≥ 6 in the other eye
6. Received and acknowledged the notice of information, and not opposed to participate in the study and to the processing of his/her personal data

* i.e., No neovascular complication, no history of injection in the last 4 months and no intention to treat in the other eye

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

120 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. 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)
2. Previously treated with faricimab (study eye)
3. Under legal guardianship or curatorship
4. Inability to fulfill the study requirements (e.g. to understand the instructions and complete the PROs questionnaires...)
5. Participation in a clinical study (interventional or non-interventional) at the time of study entry

Date of first enrolment

15/10/2026

Date of final enrolment

15/04/2028

Locations

Countries of recruitment

France

Sponsor information

Organisation

Roche (France)

ROR

<https://ror.org/01mqmer16>

Funder(s)

Funder type

Funder Name

Roche France

Alternative Name(s)

Roche

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

France

Results and Publications

Individual participant data (IPD) sharing plan

Upon study completion and publication, qualified researchers may request access to individual patient level clinical data. Request will have to be sent to: data_sharing.france@roche.com

IPD sharing plan summary

Available on request