

# Incidence of Retinal Vasculitis With or Without Retinal Vascular Occlusion Among Eyes Treated With Approved Anti-Vascular Endothelial Growth Factor Agents in Neovascular Age-Related Macular Degeneration or Diabetic Macular Edema

**First published:** 06/12/2023

**Last updated:** 22/08/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS107730

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### Study ID

107731

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### DARWIN EU® study

No

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### Study countries

United States

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### **Study description**

This is a secondary data use, retrospective observational cohort study. The study will analyze anonymized electronic health record (EHR) data from private retina specialists in the United States to assess the incidence of retinal vasculitis (RV), RV with retinal vascular occlusion (RO), and intraocular inflammation (IOI) (including RV) with RO among eyes with neovascular age-related macular degeneration (nAMD) or diabetic macular edema (DME). Incidence will be assessed among eyes treated with intravitreal (IVT) anti-vascular endothelial growth factor (VEGF) agents. The EHR (Vestrum Health Database) records longitudinal information on patient diagnosis, treatments, and outcomes, which allows the assessment of incident adverse events (AEs) and the temporality of treatments relative to the AEs. The selected database also contains data on visual acuity (VA), which allows for the assessment of potential vision changes following the occurrence of an AE. Diagnosis of nAMD, DME, and AEs will be identified using International Classification of Diseases 9/10 Clinical Modification (ICD-9/10-CM) diagnosis codes. Although Vestrum Health data are available from 1 January 2014, the appropriate study period will be determined based on the amount of data accrued across all treatment agents of interest, taking into consideration any potential surveillance or reporting bias such as that due to increased awareness of these AEs following brolocizumab launch. Inclusion criteria: eyes diagnosed with nAMD or DME that received at least 1 anti-VEGF treatment during the study period following the date of the index diagnosis; patients who were 18 years or older at the index anti-VEGF treatment; eyes with at least one visit following the index anti-VEGF treatment. Exclusion criteria: eyes with an incident IOI, RV, or RO on or prior to the index anti-VEGF treatment date.

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### **Study status**

Ongoing

## **Research institutions and networks**

# Institutions

## F. Hoffmann-La Roche

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Contact details

### Study institution contact

Trial Information Support Line TISL [global-roche-genentech-trials@gene.com](mailto:global-roche-genentech-trials@gene.com)

Study contact

[global-roche-genentech-trials@gene.com](mailto:global-roche-genentech-trials@gene.com)

### Primary lead investigator

Gloria Chi

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 09/10/2023

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### Study start date

Actual: 20/10/2023

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### **Data analysis start date**

Planned: 30/09/2026

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### **Date of final study report**

Planned: 30/09/2027

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

F. Hoffmann-La Roche, Ltd.

## Study protocol

[Prot CR45271 faricimab v2, Published Output-1\\_signed\\_20231206\\_Redacted.pdf](#)  
(659.02 KB)

[Prot CR45271 faricimab v3, Published Output-1\\_Redacted.pdf](#) (706.13 KB)

## Regulatory

### **Was the study required by a regulatory body?**

No

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### **Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 3 (required)

# Other study registration identification numbers and links

CR45271

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition  
Human medicinal product

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**Study type:**

Non-interventional study

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**Data collection methods:**

Secondary use of data

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**Main study objective:**

Assess and compare the incidence of RV, RV with RO, and IOI (including RV) with RO events across eyes treated with approved IVT anti-VEGF agents after diagnosis of nAMD or DME as recorded in the EHR database.

## Study Design

## **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Medicinal product name**

AVASTIN

BEOVU

BYOOVIZ

EYLEA

LUCENTIS

VABYSMO

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### **Medicinal product name, other**

Cimerli

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### **Study drug International non-proprietary name (INN) or common name**

AFLIBERCEPT

BEVACIZUMAB

BROLUCIZUMAB

FARICIMAB

RANIBIZUMAB

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### **Anatomical Therapeutic Chemical (ATC) code**

(S01LA04) ranibizumab

ranibizumab

(S01LA05) aflibercept

aflibercept

(S01LA06) brolocizumab

brolocizumab

(S01LA08) bevacizumab

bevacizumab

(S01LA09) faricimab

faricimab

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### **Medical condition to be studied**

Neovascular age-related macular degeneration

Diabetic retinopathy

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### **Additional medical condition(s)**

Diabetic macular edema

## Population studied

### **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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### **Estimated number of subjects**

250000

## Study design details

### **Setting**

The study will include patient eyes from the Vestrum Health database, which includes data from EHRs from private retina specialists in the United States. Diagnosis of nAMD, DME, and AEs will be identified using ICD-9/10-CM diagnosis codes. Eyes not coming from active practices in the Vestrum database will not be included. Although Vestrum Health data are available from 1 January 2014, the appropriate study period will be determined based on the amount of data accrued across all treatment agents of interest, taking into consideration any potential surveillance or reporting bias such as that due to increased awareness of these events following brolocizumab launch.

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### **Outcomes**

- Incidence of RV, RV with RO, and IOI (including RV) with RO events across eyes treated with approved IVT anti-VEGF agents after diagnosis of nAMD or DME;
  - Summarize the demographic and clinical characteristics of study eyes;
  - Among eyes with events, summarize the characteristics of anti-VEGF treatments received, including but not limited to the number of injections received, type of anti-VEGF agents received, time to event, and vision change and severe vision loss following the event
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### **Data analysis plan**

The primary analyses involve identifying the occurrence of the following adverse events: RV, RV with RO, and IOI (including RV) with RO among eyes with nAMD or DME. Eyes with each retinal indication and event will be identified using ICD-9/10-CM codes. Among eyes with multiple indications, eyes will be assigned to the first retinal indication diagnosed. The incidence of RV, RV with RO, IOI (including RV) with RO may be summarized using n (%) patient eyes at risk with events, the number of events per 1,000 injections (or 10,000 injections, etc. as appropriate), or the incidence rate (number of events/eye-time). The relative risk of RV, RV with RO, and IOI (including RV) with RO events by different anti-VEGF agents compared to a reference agent will be calculated.

## **Data management**



The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### **Data source(s), other**

Vestrum Health United States

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### **Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

[Other](#)

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### **Data sources (types), other**

Routine electronic health records from retina specialists

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No