# Evaluation of Physician Knowledge of Safety and Safe Use Information for Aflibercept Administered by Intravitreal Injection in Europe: A Follow-up Physician Survey

**First published:** 04/09/2019

**Last updated:** 01/04/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS30727

**Study ID**

40458

**DARWIN EU® study**

No

**Study countries**

France

Germany

Italy

Spain

United Kingdom

**Study description**

The study will be an observational, cross-sectional study of knowledge, understanding, and self-reported behavior among a sample of physicians with recent aflibercept experience in a total of up to 5 European countries. Physicians from a physician panel will be invited to complete a brief web-based structured questionnaire regarding their knowledge of key safety information in the aflibercept educational materials.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### RTI Health Solutions (RTI-HS)

France

Spain

Sweden

United Kingdom

United Kingdom (Northern Ireland)

United States

**First published:** 21/04/2010

**Last updated:** 13/03/2025

Institution | Not-for-profit | ENCePP partner

# Contact details

**Study institution contact**

Bayer Clinical Trials BAYER AG clinical-trials-contact@bayer.com

**Study contact**

clinical-trials-contact@bayer.com

**Primary lead investigator**

Bayer Clinical Trials BAYER AG

**Primary lead investigator**

# Study timelines

**Date when funding contract was signed**

Actual: 22/03/2019

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**Study start date**

Planned: 01/10/2019

Actual: 08/10/2019

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**Date of final study report**

Planned: 01/12/2020

Actual: 21/08/2020

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Bayer AG

## Study protocol

20285_Study Protocol_V2.0_2018-10-26_Redacted.pdf (6.84 MB)

## Regulatory

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

Yes

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

EU RMP category 3 (required)

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

**Main study objective:**

Measure physician knowledge and understanding of the key information in the revised educational material, with particular focus on knowledge of concepts that were of key concern in the previous survey

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(S01LA05) aflibercept

aflibercept

**Medical condition to be studied**

Macular degeneration

## Population studied

**Short description of the study population**

This study will be conducted with physicians (ophthalmologists) who prescribe and/or administer aflibercept in the target countries.

Eligibility criteria

• Has signed informed consent

• Is a licensed and practicing ophthalmologist

• Has prescribed and/or administered aflibercept to at least one patient in the past 6 months

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**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**

400

## Study design details

**Outcomes**

Percentage of physicians responding correctly to each individual knowledge question

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**Data analysis plan**

The analyses will be descriptive in nature and will include detailed review of responses to individual questions and potential summary measures across

logical grouping of response items.

## Documents

**Study results**

20285_EU PAS Abstract_Redacted_V1.0_2021-04-06.pdf (371.94 KB)

**Study report**

20285_CSR_V1.0_2020-08-21_Redacted.pdf (4.09 MB)

# Data management

## ENCePP Seal

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 sources (types)**

Other

**Data sources (types), other**

Physician survey

## Use of a Common Data Model (CDM)

**CDM mapping**

No

# Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

# Data characterisation

**Data characterisation conducted**

No