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





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

DTI Hoolth Colutions (DTI HC)
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

Study start date

Planned: 01/10/2019

Actual: 08/10/2019

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:

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

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)

Estimated number of subjects

400

Study design details

Outcomes

Percentage of physicians responding correctly to each individual knowledge question

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