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

PURI

https://redirect.ema.europa.eu/resource/40458

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

Study contact

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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:

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)

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

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