

# Evaluation of Physician and Patient Knowledge of Safety and Safe Use Information for Aflibercept in Europe: An Observational Postauthorisation Study

**First published:** 19/06/2015

**Last updated:** 05/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS9991

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### Study ID

23134

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### DARWIN EU® study

No

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### Study countries

 France

 Germany

 Italy

 Spain

 United Kingdom

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## Study description

The study will be an observational, cross-sectional study of knowledge, understanding, and self-reported behavior among a sample of physicians and patients with recent aflibercept experience in a total of up to five European countries.

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## 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**

Richard Gale, MD, York Hospital York, UK, Prof.  
Sascha Fauser, Univ. of Cologne Cologne, DE, Joel  
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## Contact details

### Study institution contact

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Study contact

[eandrews@rti.org](mailto:eandrews@rti.org)

### Primary lead investigator

Elizabeth Andrews

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 20/06/2013

Actual: 20/06/2013

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### Study start date

Planned: 01/12/2015

Actual: 07/12/2015

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

Planned: 15/03/2017

Actual: 05/06/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Bayer Pharma AG

## Study protocol

[EM\\_Protocol\\_Final after EMA review\\_v3\\_11 Feb 2015ENCePP.pdf](#) (961.69 KB)

## Regulatory

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

Yes

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Primary data collection

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**Main study objective:**

The primary objective of this study is to measure physician and patient knowledge and understanding of the key information contained in the aflibercept educational materials: the prescriber guide and video, and the patient booklet "Your guide to EYLEA," patient information leaflet, and audio CD.

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(S01LA05) aflibercept

aflibercept

## Population studied

## **Short description of the study population**

Physicians and patients with recent aflibercept experience in a total of up to five European countries (the United Kingdom, Germany, France, Spain, and Italy).

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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**

1250

## **Study design details**

### **Outcomes**

1) Knowledge and understanding among physicians regarding key safety information contained in the educational materials: the prescriber guide and video  
2) Knowledge and understanding among patients regarding key safety information contained in the educational materials: the patient booklet “Your guide to EYLEA,” patient information leaflet, and audio CD.

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### **Data analysis plan**

Analyses will include detailed review of responses to individual questions as well as potential summary measure across logical grouping of response items. Physician results will be stratified by country and other logical variables. Patient results will be stratified by country and other logical variables, potentially

including a measure of the knowledge level of their physician. A detailed analysis plan describing methods of analysis and presentation and including table shells will be developed before analysis of data is initiated. In addition to a description of the analysis of the questionnaire data, the analysis plan will describe any planned comparisons of participants and non-participants.

## Documents

### Study results

[16526\\_EU-PAS\\_Abstract\\_CTP.pdf](#) (61 KB)

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### Study report

[16526\\_Eylea Europe RMS\\_Final Report\\_Bayer\\_15Nov2017.pdf](#) (6.3 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](#)

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### Data sources (types), other

Cross-sectional data collection through an interviewer administered questionnaire for the patient assessment and a web-based questionnaire for the physician assessment.

## 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**

Unknown