

# Efetividade de Materiais Educacionais para Profissionais de Saúde e População geral Alvo enquanto Medidas Adicionais de Minimização de Risco para Vabysmo®, Eylea® e Lucentis® - O Estudo MARVEL

**First published:** 21/09/2023

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Study

Planned

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/106810>

### EU PAS number

EUPAS106809

### Study ID

106810

### DARWIN EU® study

No

## Study countries

☐ Portugal

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## Study description

Ophthalmological diseases affect all age groups and are increasingly prevalent. Pathologies such as age-related macular degeneration (AMD), diabetic macular edema (DME), retinal vein occlusion (RVO), and choroidal neovascularization (CNV) affect the posterior region of the eye, and have common treatment options available. The medicines Vabysmo®, Eylea® and Lucentis® are classified as Antineovascularization Agents and are used in the treatment of these ocular pathologies. Educational programs aim to adequately inform patients about the risks associated with the medicine, and as such their effectiveness must be guaranteed.

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## Study status

Planned

# Research institutions and networks

## Institutions

[Association for Innovation and Biomedical Research on Light and Image \(AIBILI\)](#)

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Institution

## Contact details

### Study institution contact

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Study contact

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### Primary lead investigator

Liseta Lemos

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/09/2023

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### Study start date

Planned: 15/09/2023

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### Data analysis start date

Planned: 31/10/2023

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### Date of final study report

Planned: 30/11/2023

## Sources of funding

- Other

## More details on funding

INFARMED I.P..

## Regulatory

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

No

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

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

#### **Main study objective:**

The objective of the study is to evaluate the effectiveness of educational materials designed to healthcare professionals and patients used as additional risk minimisation measures for Vabysmo® (faricimab), Eylea® (aflibercept) and Lucentis® (ranibizumab).

## Study Design

## **Non-interventional study design**

Cohort

## 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**

500

## Study design details

### **Outcomes**

For healthcare professionals and the general population target, evaluate: - Receiving and viewing educational materials used as additional risk minimisation measures for Vabysmo® (faricimab), Eylea® (aflibercept) and Lucentis® (ranibizumab). - The level of knowledge of the key messages described in the educational materials used as additional risk minimisation measures for Vabysmo® (faricimab), Eylea® (aflibercept) and Lucentis® (ranibizumab).

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### **Data analysis plan**

Descriptive statistics will be used. Frequency distributions with 95% confidence intervals (CI) will be calculated for all responses. The data will be stratified by

target group: health care professionals and patients/caregivers and by medicine.

## Data management

### ENCePP Seal

#### **Signed checklist for study protocols**

[ENCePPChecklistforStudyProtocols\\_preenchido.pdf](#)(290.84 KB)

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### Data sources

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

[Other](#)

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

Prospective patient-based data collection

### 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