

# European Drug Usage Survey for Amyvid (I6E-MC-AVBF)

**First published:** 12/12/2014

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

Study

Finalised

## Administrative details

### EU PAS number

EUPAS6736

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### Study ID

24810

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### DARWIN EU® study

No

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### Study countries

 Italy

 Spain

 United Kingdom

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### Study description

This is a survey of physicians who refer patients for Amyvid PET scans. This study seeks to establish the usage patterns of Amyvid in European clinical practice.

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### Real World Evidence Solutions, IMS Health

 France

**First published:** 06/09/2011

**Last updated:** 20/08/2024

**Institution**

Other

## Contact details

### Study institution contact

Claudia Salinas [claudia.salinas@lilly.com](mailto:claudia.salinas@lilly.com)

**Study contact**

[claudia.salinas@lilly.com](mailto:claudia.salinas@lilly.com)

### Primary lead investigator

Claudia Salinas

## Study timelines

### **Date when funding contract was signed**

Planned: 15/12/2014

Actual: 15/12/2014

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### **Study start date**

Planned: 15/12/2014

Actual: 17/12/2014

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

Planned: 01/06/2017

Actual: 28/10/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company

## Study protocol

[European drug usage survey for Amyvid I6E-MC-AVBF - redacted approved protocol.pdf](#) (1.04 MB)

[AVBF PASS Protocol\\_Redacted.pdf](#) (629.1 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:

Disease /health condition

Human medicinal product

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#### Study type:

Non-interventional study

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#### Scope of the study:

Drug utilisation

#### Data collection methods:

Primary data collection

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#### Main study objective:

To assess the usage patterns of Amyvid in European clinical practice, To assess the level of off-label use in European clinical practice.

## Study Design

## **Non-interventional study design**

Cross-sectional

## Study drug and medical condition

### **Anatomical Therapeutic Chemical (ATC) code**

(V09AX05) florbetapir (18F)

florbetapir (18F)

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### **Medical condition to be studied**

Dementia Alzheimer's type

## Population studied

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

Healthcare providers who were referrers for Amyvid PET scans with following criteria:

- physicians in active clinical practice
  - hospital- or office-based,
  - who practice in an EU country
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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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## Special population of interest

Other

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## Special population of interest, other

Patients with Dementia Alzheimer's type

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## Estimated number of subjects

100

# Study design details

## Data analysis plan

Reasons for the Amyvid referral will be summarized using responses to the survey questions. The level of off-label use will be reported for each relevant question as a proportion of the total responses and as the total number of questions consistent with off-label use. Results will also be analysed by temporal period (1, 2, or 3 years elapsed since commercial launch of Amyvid) to evaluate if there are trends in patterns of Amyvid use. Reasons for non-response will be evaluated to assess the potential existence of selection bias. Additional information is available in the report.

# Documents

## Study results

[AVBF PASS FSR\\_Redacted.pdf](#) (943.24 KB)

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# 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

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**

Unknown