

# Post-Authorisation Survey of Nuclear Medicine Physicians and Radiologists in Europe to Evaluate Trends and Patterns in VIZAMYL™ Use in Everyday Clinical Practice in the EU

**First published:** 10/09/2018

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS25167

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### Study ID

26712

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### DARWIN EU® study






No

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### Study countries

 Austria

 Belgium

-  Finland
  -  Germany
  -  Italy
  -  Slovakia
  -  Sweden
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### **Study description**

This drug utilisation study, is designed in response to request from EMA, will retrospectively assess the actual use of VIZAMYL PET scans in the everyday clinical settings and determine the level of off-label use in Europe. The study will retrospectively survey VIZAMYL readers in European countries where VIZAMYL is commercially available and where high use is expected during the study period to determine trends and patterns of VIZAMYL use in everyday clinical practice.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

Multiple centres: 50 centres are involved in the study

## Contact details

**Study institution contact**

Paul Sherwin paulsherwin@ge.com

Study contact

[paulsherwin@ge.com](mailto:paulsherwin@ge.com)

**Primary lead investigator**

Paul Sherwin

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 03/12/2018

Actual: 12/03/2018

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**Study start date**

Planned: 12/02/2019

Actual: 01/07/2020

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**Date of final study report**

Planned: 20/08/2020

Actual: 29/04/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GE HealthCare

## Study protocol

[GE-067-028 CPR v5.pdf](#) (1.45 MB)

## Regulatory

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

Yes

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

To retrospectively determine post-authorisation use of VIZAMYL in everyday clinical practice in the EU.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Retrospective post-authorisation study

## Study drug and medical condition

**Medical condition to be studied**

Dementia Alzheimer's type

## Population studied

**Short description of the study population**

A survey of physicians practicing nuclear medicine or radiologist in at least one of the target countries, had reviewed at least three VIZAMYL™ scans.

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### **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
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### **Special population of interest**

Other

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### **Special population of interest, other**

Patients with Alzheimer's disease

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### **Estimated number of subjects**

0

## Study design details

### **Outcomes**

Summary across survey respondents of reported percentage of patients referred for a VIZAMYL scan for the indication listed in the SmPC. This will be determined separately for each survey round (3 rounds, conducted at 12-month intervals). To retrospectively describe use in everyday clin. practice with regard to: Indication, admin. dose of radioactivity, body region imaged, time from dosing to scan initiation, duration of scanning, type of other images used to assist in interpret. of images, percent. of patients with a contraind who were scanned and not scanned, percent. of readers who have compl training in interpret of PET images

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## **Data analysis plan**

Tabulations of summary statistics, graphical presentations, and statistical analyses will be performed using SAS software, Version 9.3 or higher.

Descriptive statistics for continuous data in summary tables will include the number of subjects in the analysis (n), mean, standard deviation, median, and range (minimum, maximum). Descriptive statistics for categorical data in summary tables will include counts and percentages. All data entered into the database will be provided in separate data listings showing individual subject values. The planning and reporting of statistical analysis will be carried out as described in the Sponsor and CRO's standard operating procedures governing clinical studies. Details of the analysis will be provided in the Statistical Analysis Plan. Missing values will not be substituted by estimated values, but treated as missing in the statistical evaluation. All data from all subjects enrolled and imaged in the study will be included in all listings.

## 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)**

**Data sources (types), other**

All survey data will be obtained from the web-based survey forms. Eligible physicians who agree to participate will be selected and demographic information about them will be collected. They will answer a series of survey questions about their recollection of personal experience using VIZAMYL in everyday clinical practice.

## 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