

# TAK-669-4018: A Survey Among Patients, Caregivers and Home Infusion Nurses Based in the European Union to Assess Their Awareness and Understanding of Educational Materials Supporting VPRIV® Infusion at Home

**First published:** 20/12/2022

**Last updated:** 17/04/2025

Study

Planned

## Administrative details

### EU PAS number

EUPAS49598

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### Study ID

49599

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### DARWIN EU® study

No

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### Study countries

- Austria
  - Belgium
  - Denmark
  - Finland
  - France
  - Germany
  - Ireland
  - Italy
  - Netherlands
  - Spain
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### **Study description**

The main purpose of this survey is to determine participants', caregivers', and nurses' understanding and use of educational material (EM) on VPRIV home treatment. EM includes an infusion diary and guide and an emergency plan related to VPRIV infusion given at home for Gaucher disease. The survey is conducted in European countries. Data will be collected directly from participants, caregivers, and nurses in form of a questionnaire, electronic or paper.

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### **Study status**

Planned

## Research institutions and networks

### Institutions

**Takeda**

**First published:** 01/02/2024

Last updated: 01/02/2024

Institution

## Contact details

### Study institution contact

Study Contact Takeda TrialDisclosures@takeda.com

Study contact

[TrialDisclosures@takeda.com](mailto:TrialDisclosures@takeda.com)

### Primary lead investigator

Study Contact Takeda

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/12/2022

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### Study start date

Planned: 30/09/2026

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### Date of final study report

Planned: 30/09/2027

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Takeda

## 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 type:**

Non-interventional study

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

Effectiveness study (incl. comparative)

Other

#### **If 'other', further details on the scope of the study**

Assessing awareness and understanding of education materials for using VPRIV®

**Main study objective:**

The main objective of this study is to assess the proportion of participants, caregivers and home infusion nurses who are aware of the Educational Material (EM) (home infusion guide, infusion diary, and safety and emergency plan), who understand the EM and use the EM.

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Medical condition to be studied**

Gaucher's disease

## Population studied

**Age groups**

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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**

60

## Study design details

### **Outcomes**

1. Percentage of Participants/Caregivers who are Aware of EM 2. Percentage of Participants/Caregivers who Understand EM 3. Percentage of Participants/Caregivers who Utilize EM 4. Percentage of Home Infusion Nurses Aware of EM 5. Percentage of Home Infusion Nurses who Understand EM 6. Percentage of Home Infusion Nurses who Utilize EM

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### **Data analysis plan**

Percentage of correct and appropriate answers about awareness and understanding of conditions of use of VPRIV® home infusion given by patients, caregivers and home infusion nurses will be assessed. Continuous variables will be described by the number of valid cases and missing data, mean, standard deviation (SD), median, Q1, Q3, minimum, and maximum. No missing data will be replaced. Categorical variables will be described as the total number and relative percentage per category. CIs of 95% will be calculated when relevant.

## 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

This is a survey among participants receiving VPRIV® home infusion, their caregivers and home infusion nurses who administer VPRIV® home infusion through non-nominative web-based questionnaires.

## 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