

# US-based cross-sectional survey in patients taking lasmiditan: Functional REstoration with rEyvow (FREE)

**First published:** 17/11/2020

**Last updated:** 13/12/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS37245

### Study ID

41778

### DARWIN EU® study

No

### Study countries

☐ United States

## Study description

The objective of the study is to assess patients' ability to return to their usual daily activities after treating a migraine attack with lasmiditan. Study data will be collected by conducting a 15-minute web-based cross-sectional survey in adult patients in US who have redeemed a REYVOW savings card and have taken lasmiditan at least once in the past month for treatment of a migraine attack.

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## Study status

Finalised

## Research institutions and networks

### Institutions

Clinical, Regulatory and Safety, Cerner Enviza

☐ Germany

**First published:** 15/03/2022

**Last updated:** 05/02/2025

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

## Contact details

### Study institution contact

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**Study contact**

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**Primary lead investigator**

Amit Qamra

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 08/07/2020

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**Study start date**

Actual: 16/11/2020

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**Data analysis start date**

Planned: 01/12/2020

Actual: 01/12/2020

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**Date of final study report**

Planned: 01/06/2021

Actual: 15/06/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company

# Study protocol

[FREE study\\_protocol\\_final.pdf](#)(1011.12 KB)

## 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 topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

The objective of the study is to assess patients' ability to return to their usual daily activities after treating a migraine attack with lasmiditan.

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Study drug International non-proprietary name (INN) or common name**

LASMIDITAN

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**Medical condition to be studied**

Migraine

## Population studied

**Short description of the study population**

Adult patients in US who have redeemed a REYVOW savings card and have taken lasmiditan at least once in the past month for treatment of a migraine attack prior to completing the survey.

Inclusion Criteria

The study will include all participants who meet the following criteria:

1. Age  $\geq 18$  at time of study
2. Enrolled in US REYVOW patient support program
3. Redeemed a REYVOW Savings Card
4. Provide informed consent to participate in the study
5. Have taken lasmiditan in the past month prior to completing the survey

#### Exclusion Criteria

Participants will be excluded from the study:

1. Cannot read or understand English
  2. Cannot use a computer or smart device with internet access
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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**

Migrane patients

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#### **Estimated number of subjects**

250

## Study design details

## Outcomes

Ability to perform and the time taken to return to usual daily activities engaged in when the migraine attack started, and Ability to return to planned activities for that day and level of impairment of those activities, Activity that was most impacted by their migraine attack prior to taking lasmiditan, the activity that the patient was most concerned about prior to taking lasmiditan, and the level of impairment of usual activities during an untreated or unsuccessfully treated attack prior to when lasmiditan was initiated

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## Data analysis plan

All study measures will be reported descriptively using means, standard deviations, medians, and 95% confidence intervals for continuous outcome variables and frequencies and percentages for categorical outcome variables. Differences between subgroups will be evaluated: analyses will be conducted to examine whether the select study outcome measures differ by each of the subgroups, using chi-square tests for categorical variables and one-way analysis-of-variance tests (ANOVAs) for continuous variables. P-values will be provided for the omnibus test (one-way ANOVA) and pair-wise testing between the groups. It should be noted that all comparisons are conditional on whether each subgroup results in adequate sample size.

# Documents

## Study results

[REYVOW FREE Report\\_ENCePP version. 14 JUN 2021\\_APPROVED.pdf](#)(5.17 MB)

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## Study publications

[Schwedt TJ, Lombard LA, Doty E, Vincent M, Mills KM, Ayer DW, et al. Functional...](#)

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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

Electronic one-time survey

## 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