

# WEUKBRE5744: European Survey of Patient and Prescriber Understanding of Risks Associated with TROBALT™ (116771)

**First published:** 14/06/2013

**Last updated:** 24/05/2024

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/42075>

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### EU PAS number

EUPAS4126

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### Study ID

42075

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### DARWIN EU® study

No

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### Study countries

Denmark

- Germany
  - Norway
  - Slovakia
  - Spain
  - Sweden
  - Switzerland
  - United Kingdom
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### Study description

This is a cross-sectional survey of prescribers and patients on the effectiveness of the physician guide and the patient information leaflet on physician and patient understanding of the significant risks of TROBALT (retigabine). This forms part of the European Risk Management Plan (RMP) requirements.

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### Study status

Finalised

## Research institutions and networks

### Institutions

#### United BioSource Corporation (UBC)

- Switzerland

**First published:** 25/04/2013

**Last updated:** 06/03/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

## Contact details

### Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Study contact

[cdr\\_mailbox@gsk.com](mailto:cdr_mailbox@gsk.com)

### Primary lead investigator

Lianna Ishihara

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 18/09/2012

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### Study start date

Actual: 18/09/2012

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### Date of final study report

Planned: 27/09/2014

Actual: 31/01/2014

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

## Study protocol

[Redacted 1166771\\_Protocol\\_Trobalt\\_EU\\_Survey\\_Amendment 11-Sep-2012\\_FINAL.pdf](#)(518.37 KB)

[WEUKBRE5744-protocol-redact.pdf](#)(622.6 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)?**

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:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Primary data collection

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**Main study objective:**

The objectives of this study are to assess patients' and prescribers' understanding and knowledge of the significant risks associated with TROBALT use as evaluated by a survey instrument.

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Name of medicine**

TROBALT

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**Medical condition to be studied**

Epilepsy

## Population studied

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

Neurologists prescribing AEDs and who have been sent the TROBALT Physician's guide.

Inclusion criteria:

1. Must have prescribed an AED at least once in the last 3 months
2. Must be on the list to which the Physician's Guide for TROBALT was distributed

Exclusion:

1. Currently an employee of GSK or UBC
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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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## **Estimated number of subjects**

350

## **Study design details**

### **Outcomes**

The primary outcome of the survey is the proportion of patients/neurologists providing correct responses to a series of questions concerning the significant risks associated with TROBALT. The risks evaluated will be those described in the TROBALT PIL and in the Physician's Guide.

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## Data analysis plan

The population for analysis will comprise all neurologists recruited into the study, meeting eligibility criteria as assessed in the survey screener, and completing the survey. The outcomes (proportion of respondents answering each question correctly) will be summarised for all countries combined, and then for all countries combined not including Germany, with a separate analysis for Germany. The sub-population for analyses will be the neurologists who have ever prescribed TROBALT. For patients, the population for analysis will be all patients included in the study who completed the survey. Patient demographics and indication for TROBALT use will be summarized. The primary outcome is the proportion of patients answering each question correctly. The countries will be combined, with and without Germany. The sub-population for analyses will be by demographic characteristics such as country.

## Documents

### Study results

[116771-clinical-study-report-redact.pdf](#)(627.41 KB)

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## Data management

### Data sources

#### Data source(s)

Drug claims information system

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## **Data sources (types)**

Other

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

Physician's 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