# Survey of prescriber understanding of specific risks associated with TROBALT (201426)

**First published:** 02/04/2014

**Last updated:** 28/05/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS6186

**Study ID**

42090

**DARWIN EU® study**

No

**Study countries**

- [ ] Austria
- [ ] Belgium
- [ ] Bulgaria
- [ ] France

- [ ] Hong Kong
- [ ] Italy
- [ ] Norway
- [ ] Poland
- [ ] Slovenia
- [ ] Spain
- [ ] Switzerland
- [ ] United Kingdom

**Study status**

Finalised

## Research institutions and networks

### Institutions

#### GlaxoSmithKline (GSK)

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

**Last updated:** 01/02/2024

**Institution**

## Contact details

**Study institution contact**

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

**Study contact**

Pharma.CDR@gsk.com

**Primary lead investigator**

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 14/02/2014

Actual: 14/02/2014

---

**Study start date**

Planned: 14/02/2014

Actual: 14/02/2014

---

**Date of final study report**

Planned: 06/04/2015

Actual: 26/08/2015

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

# Study protocol

prj2250-protocol-redact.pdf(736.84 KB)

201426-protocol-amend-redact.pdf(765.63 KB)

# Regulatory

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

No

---

**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

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Other

**If ‘other’, further details on the scope of the study**

Physician survey

**Data collection methods:**

Primary data collection

---

**Main study objective:**

The objective of this study is to assess prescribers’ awareness of recent label changes, including the appropriate patient population related to retigabine as evaluated by a survey instrument.

## Study Design

**Non-interventional study design**

Cross-sectional

Other

---

**Non-interventional study design, other**

Physician survey

## Study drug and medical condition

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

RETIGABINE

## Population studied

**Short description of the study population**

Physicians prescribing AEDs and who have been sent a DHCP letter in Austria, Belgium, France, Hongkong,Italy, Norway, Poland, Slovakia, Spain, Switzerland and the United Kingdom.

Physicians will be required to meet all the following inclusion criteria:

1. Must manage patients with epilepsy.
2. Must have prescribed an AED at least once in the last 6 months.
3. Must be on the list to which a DHCP letter was distributed in June 2013.

Physicians meeting any of the following criteria will not be eligible to take the survey:

1. Currently an employee of GSK or UBC.

---

**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)

---

**Estimated number of subjects**

0

# Study design details

**Outcomes**

The proportion of physicians providing correct responses to a series of questions concerning specific risks associated with retigabine

---

**Data analysis plan**

The outcome of the survey is the proportion of physicians providing correct responses to a series of questions concerning specific risks associated with retigabine. Additional analyses will compare the level of understanding between physicians who have prescribed retigabine and those who have never or not recently prescribed the product.

## Documents

**Study results**

gsk-201426-clinical-study-report-redact.pdf(1.59 MB)

# 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

**Data sources (types), other**

Physician survey

## Use of a Common Data Model (CDM)

**CDM mapping**

No

# Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

# Data characterisation

**Data characterisation conducted**

No