# Knowledge survey to assess the effectiveness of educational materials among healthcare professionals who prescribe Lemtrada® (alemtuzumab)

**First published:** 29/05/2020

**Last updated:** 14/03/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS35547

**Study ID**

35666

**DARWIN EU® study**

No

**Study countries**

- ☐ Belgium
- ☐ Denmark
- ☐ Germany

- [ ] Greece
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

**Study description**

The overall objective of the survey is to assess descriptively the knowledge level of Healthcare Professionals (HCPs) with regard to educational messages and thus the effectiveness of the educational materials to support the safe use of LEMTRADA:Research questions:1. What is the HCP's understanding and awareness of the risks associated with use of LEMTRADA?2. What is the HCP's knowledge of the key safety messages in the content of the HCP guide and HCP checklist?3. What is the HCP's knowledge and understanding of the risk minimization activities to be undertaken in relation to LEMTRADA?

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Sanofi

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

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

Institution

# Contact details

**Study institution contact**

Trial Transparency Team Trial Transparency Team contact-us@sanofi.com

**Study contact**

contact-us@sanofi.com

**Primary lead investigator**

Trial Transparency Team Trial Transparency Team

**Primary lead investigator**

# Study timelines

**Date when funding contract was signed**

Planned: 01/12/2015

Actual: 05/01/2016

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**Study start date**

Planned: 01/12/2015

Actual: 01/03/2016

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**Data analysis start date**

Planned: 01/02/2016

Actual: 01/08/2016

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**Date of interim report, if expected**

Planned: 07/03/2016

Actual: 07/11/2016

**Date of final study report**
Planned: 06/11/2017

Actual: 05/11/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Sanofi

## Study protocol

ALEMLC09614_2015-11-30 LEMTRADA_HCP_PROTOCOL 1 7-WAVE 1-final.pdf
(523.19 KB)

ALEMLC09614_2017-05-08 LEMTRADA_HCP_PROTOCOL 1.8 - WAVE2-2.pdf
(113.22 KB)

## Regulatory

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

Yes

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

EU RMP category 3 (required)

## Other study registration identification numbers and links

# Methodological aspects

## Study type

## Study type list

**Study topic:**

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 overall objective of the survey is to assess descriptively the knowledge level of Healthcare Professionals (HCPs) with regard to educational messages and thus the effectiveness of the educational materials to support the safe use of LEMTRADA.

## Study Design

**Non-interventional study design**

Cross-sectional

# Study drug and medical condition

**Name of medicine**

LEMTRADA

# Population studied

**Short description of the study population**

Healthcare Professional (HCPs) involved in the treatment of MS using Lemtrada.

Inclusion criteria

• HCP is a neurologist/MS specialist

• HCP has prescribed Lemtrada to at least one patient within the past 6 months

• HCP supplies informed consent by ticking a box on the survey website.

Exclusion criteria

• HCP has not prescribed Lemtrada within the past 6 months

• Participation in the questionnaire in Wave 1.

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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**

0

# Study design details

**Outcomes**

Awareness of HCP and patient educational materials, knowledge of the key points of the educational materials. Subgroup comparisons based on country and specialist role.

**Data analysis plan**

Descriptive statistics including HCP understanding and awareness of educational materials at 18 and 36 months after the launch of Lemtrada.

## Documents

**Study results**

riskmgtsystem-hcp-survey-report.pdf(4.1 MB)

# Data management

## Data sources

**Data sources (types)**

Other

**Data sources (types), other**

Cross-sectional data were collected on HCP characteristics.

## 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