

# International LEMTRADA Pregnancy Exposure Cohort in Multiple Sclerosis (OBS13436)

**First published:** 08/10/2014

**Last updated:** 16/02/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS7574

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### Study ID

50049


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### DARWIN EU® study


No

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### Study countries

 Australia

 Austria

 Belgium

 Canada

-  Denmark
  -  Germany
  -  Italy
  -  Netherlands
  -  Spain
  -  Sweden
  -  Switzerland
  -  United Kingdom
  -  United States
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## **Study description**

A voluntary post authorization safety study (PASS). An international, prospective, observational cohort study (registry) of pregnancy outcomes in women with multiple sclerosis exposed to LEMTRADA during pregnancy. The overall goal of the study is to evaluate pregnancy outcomes in women exposed to LEMTRADA during pregnancy and to determine if the risk of any adverse pregnancy outcomes in these women exceeds the risks in women with MS who have not been exposed to LEMTRADA during pregnancy. Specific outcomes to be assessed include: spontaneous abortion, stillbirth, fetal major malformations, preterm birth, and small for gestational age at birth. To further characterize prenatally-exposed live births, outcomes in the neonatal and pediatric periods up to one year of age will be assessed pending available data.

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## **Study status**

Finalised

## **Research institutions and networks**

### **Institutions**

## Sanofi

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

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Institution

## Contact details

### Study institution contact

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

Study contact

[contact-US@sanofi.com](mailto: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: 08/09/2014

Actual: 08/09/2014

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### Study start date

Planned: 30/11/2014

Actual: 01/09/2015

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### **Date of final study report**

Planned: 04/11/2022

Actual: 09/11/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Genzyme a Sanofi Company

## Study protocol

[rdct-obs13436-amended-protocol02-pdfa.pdf](#) (489.47 KB)

## 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 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  
Safety study (incl. comparative)

**Data collection methods:**

Combined primary data collection and secondary use of data

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**Main study objective:**

To assess adverse pregnancy outcomes in women exposed to LEMTRADA during pregnancy. Pregnancy outcomes assessed will include: spontaneous abortion, stillbirth, fetal major malformations, preterm birth, and small for gestational age at birth.

## Study Design

**Non-interventional study design**

Cohort  
Other

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**Non-interventional study design, other**

International, observational registry

## Study drug and medical condition

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

ALEMTUZUMAB

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### **Medical condition to be studied**

Multiple sclerosis

## **Population studied**

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

Pregnant women with multiple sclerosis (MS) who had any pregnancy exposure to LEMTRADA between 10 August 2015 and 22 November 2021 from North America, Europe, and the rest of the world.

Inclusion criteria:

- Women with MS who were or became pregnant within the period of time between the first

infusion of a course of treatment with LEMTRADA to 4 months after their last infusion for

that course.

- Able and willing to provide informed consent for study participation and the requirement

of the study. Informed consent will be obtained at the time of enrollment in accordance

with local regulatory requirements.

Exclusion criteria:

- Previous enrollment in this study for a previous pregnancy.

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### **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
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### **Special population of interest**

Other

Pregnant women

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### **Special population of interest, other**

Patients with multiple sclerosis

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### **Estimated number of subjects**

42

## Study design details

### **Outcomes**

To determine if the risk of any adverse pregnancy and fetal outcomes in women exposed to LEMTRADA exceeds the risks in women with MS who have not been exposed to LEMTRADA during pregnancy. To further characterize prenatally-exposed live births, outcomes in the neonatal and pediatric periods up to one year of age, which will be assessed pending available data.

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### **Data analysis plan**

Rates and 95% confidence intervals (CI) of pregnancy outcomes for women exposed to LEMTRADA during pregnancy will be calculated. These rates will be compared with corresponding rates in a primary external comparison cohort of women with MS who have not been exposed to LEMTRADA during pregnancy.

## Documents

## Study results

[rdct-obs13436-csr-abstract-pdfa.pdf](#) (740.04 KB)

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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)

[Drug registry](#)

## 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