

# Teriflunomide Pregnancy Outcome Exposure Registry: An OTIS Autoimmune Diseases in Pregnancy Project (OBS13499)

**First published:** 04/01/2017

**Last updated:** 21/06/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS17065

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### Study ID

41601


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### DARWIN EU® study

No

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### Study countries

 Canada

 United States

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### Study description

This is a North American prospective, observational, exposure cohort study of pregnancy outcomes in women with multiple sclerosis (MS) who are exposed to teriflunomide during pregnancy. The outcomes in women exposed to teriflunomide will be compared to those observed in two comparison groups: one in women with MS who have not been exposed to teriflunomide during pregnancy, and the other in women without MS.

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### Organization of Teratology Information Specialists (OTIS)

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

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Institution

## Contact details

### Study institution contact

Team Transparency contact-us@sanofi.com

Study contact

[contact-us@sanofi.com](mailto:contact-us@sanofi.com)

## Primary lead investigator

Team Transparency

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 12/02/2013

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### Study start date

Actual: 25/04/2013

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### Date of final study report

Planned: 29/03/2024

Actual: 22/05/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Sanofi

## Study protocol

[rdct-obs13499-protocol.pdf](#) (788.35 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 type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

#### **Main study objective:**

To assess pregnancy outcomes in women with multiple sclerosis (MS) who are exposed to teriflunomide during pregnancy.

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

AUBAGIO

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

TERIFLUNOMIDE

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**Anatomical Therapeutic Chemical (ATC) code**

(L04AA31) teriflunomide

teriflunomide

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**Medical condition to be studied**

Multiple sclerosis

## Population studied

**Age groups**

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

Pregnant women

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**Estimated number of subjects**

325

## Study design details

**Outcomes**

To evaluate any potential increase in the risk of major birth defects, in the first year of life, in teriflunomide-exposed pregnancies. To evaluate the potential effect of teriflunomide-exposure on other adverse pregnancy outcomes including any potential pattern of minor birth defects, spontaneous abortion, stillbirth, preterm delivery, small for gestational age at birth and at 1 year follow-up.

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### **Data analysis plan**

Comparison of the pregnancy outcomes in women exposed to teriflunomide for the treatment of MS, with those observed in women with MS who have not been exposed to teriflunomide during pregnancy, and to the pregnancy outcomes of women without MS.

## Documents

### **Study report**

[rdct-obs13499-addendum to interim report 10.pdf](#) (144.47 KB)

## 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**

Prospective patient-based data collection

## **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