

# An International Pregnancy Exposure registry of Women With Multiple Sclerosis (MS) exposed to Teriflunomide (OBS12751)

**First published:** 21/01/2014

**Last updated:** 25/06/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS5602

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### Study ID

43003

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### DARWIN EU® study

No

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### Study countries

- Australia
- Austria
- Belgium
- Denmark

- Finland
  - France
  - Germany
  - Greece
  - Ireland
  - Italy
  - Netherlands
  - Norway
  - Spain
  - Sweden
  - Switzerland
  - United Kingdom
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### **Study description**

This is a voluntary, international, prospective, observational, non-interventional, exposure registration study examining the risk of major congenital malformations (birth defects) among the infants and fetuses of women with MS who are exposed to teriflunomide during pregnancy. The birth defect rate will be compared to published birth defect rates from the EUROCAT (EUROCAT, 2013).

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

## Syneos Health

United Kingdom

**First published:** 23/04/2015

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

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

## INC Research

### 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

Stéphanie Tcherny-Lessenot

**Primary lead investigator**

### Study timelines

#### Date when funding contract was signed

Planned: 28/06/2013

Actual: 28/06/2013

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### **Study start date**

Planned: 31/01/2015

Actual: 25/11/2015

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

Planned: 30/09/2023

Actual: 31/07/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Sanofi

## Study protocol

[rdct-obs12751-amended-protocol03-pdfa.pdf](#) (1.85 MB)

## 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 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:**

Primary data collection

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**Main study objective:**

This registry aims to monitor pregnancies among women with MS who were inadvertently exposed to teriflunomide during pregnancy to evaluate the risk of birth defects in their infants and fetuses. In addition, the registry will evaluate the potential impact of prenatal teriflunomide exposure on pregnancy and infant health, growth, and development.

The primary objective of this registry is:

-To compare the rate of birth defects (major congenital malformations diagnosed up to one year of age, fetal deaths occurring at 20 gestation weeks or later, and termination of pregnancy for fetal anomaly following prenatal diagnosis (TOPFA)) with the rate of the same birth defects reported by the European Surveillance of Congenital Anomalies (EUROCAT), a population based birth defect surveillance system.

## Study Design

## **Non-interventional study design**

Cohort

Other

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## **Non-interventional study design, other**

Voluntary, international, prospective, observational, exposure registration study

# Study drug and medical condition

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

TERIFLUNOMIDE

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## **Medical condition to be studied**

Multiple sclerosis

# Population studied

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

The study population included pregnant women with multiple sclerosis (MS) received treatment with teriflunomide identified from the multiple countries: Australia, Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Norway, Spain, Sweden, Switzerland, and the United Kingdom.

Inclusion criteria:

- Is pregnant
- Has MS and was exposed to teriflunomide during pregnancy as defined below:
  - a/ inadvertently received any teriflunomide dose at any time during pregnancy (from the first day of the last menstrual period to end of pregnancy), regardless

of the dose or duration of use, OR b/ received any teriflunomide dose prior to pregnancy start and had teriflunomide plasma concentration greater than or equal to 0.02 mg/L measured during pregnancy and available/retrievable for the confirmation of enrolment

- Has provided written informed consent to participate in the registry, through her HCP
- Authorizes the release of medical information to the National Coordinator for herself and her live born infant(s), as applicable
- Agrees to provides contact information for herself, her HCP, and her infant's HCP, as applicable

Exclusion criteria

- Does not receive health care in a country in which the registry is operational
  - Was participating in a clinical trial investigating teriflunomide at the time of pregnancy exposure
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### **Age groups**

- Adults (18 to < 46 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**

196

## Study design details

## Outcomes

major congenital malformations diagnosed up to one year of age, fetal deaths occurring at 20 gestation weeks or later, and termination of pregnancy for fetal anomaly following prenatal diagnosis (TOPFA), Pregnancy outcomes including live born infants, recognized spontaneous abortions occurring at less than 20 gestation weeks, fetal deaths occurring at 20 gestation weeks or later, induced abortions without reported evidence of birth defects, TOPFA, ectopic pregnancy, and molar pregnancy Pregnancy exposure to teriflunomide and the elimination procedure

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## Data analysis plan

For the primary analysis, the rate of birth defects among infants and fetuses prenatally-exposed to teriflunomide and reported to the Registry is calculated by dividing the number of birth defects among live born infants (LB), fetal deaths (>20 weeks' gestation) (FD), and TOPFA (at any gestational age) by the total number of LB, FD, and TOPFA with and without birth defects.

## Documents

### Study results

[rdct-obs12751-pass-final-abstract-2023-PDFA.pdf](#) (885.59 KB)

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## Data management

## ENCePP Seal

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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