

# Vedolizumab-5001: Organization of Teratology Information Specialists (OTIS) Vedolizumab Pregnancy Exposure Registry

**First published:** 08/01/2016

**Last updated:** 21/11/2024

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/49443>

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### EU PAS number

EUPAS11681

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### Study ID

49443

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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 prospective, multicenter observational cohort study of pregnant women with ulcerative colitis (UC) and Crohn's disease (CD), who are at least 1 dose exposed at any time from last menstrual period (LMP) during pregnancy to vedolizumab (Entyvio) or other biological agents for UC or CD. The purpose of this study is to monitor planned and unplanned pregnancies in UC or CD female patients exposed to vedolizumab and to evaluate any possible association between this medication and pregnancy outcome, including the health of the mother, fetus, and infant. The study population of pregnant women would be drawn from 3 sources: OTIS Network, pregnant women who spontaneously contact the study research center or the sponsor or who are referred by their health care practitioners (HCP) in North America and women in North America who become pregnant while participating in other Entyvio clinical studies being undertaken by the sponsor. The planned total duration of the study is 6 years and cohort enrollment will be done before 20 weeks of gestation period and intake interviews would be scheduled telephonically. If subject is enrolled and intake interview is conducted between 16 and 20 week's gestation, only one interim interview will be conducted during pregnancy at 32-34 week's gestation. Outcome interview would be conducted within 0 to 6 weeks after delivery, dysmorphological examination of live infants would be conducted within 0 to 12 months after delivery and pediatric medical record review and questionnaire would be held 1 year after delivery.

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### **Study status**

Finalised

## **Research institutions and networks**

# Institutions

## Organization of Teratology Information Specialists (OTIS)

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

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

Institution

## Contact details

### Study institution contact

Christina Chambers

Study contact

[trialsdisclosures@takeda.com](mailto:trialsdisclosures@takeda.com)

### Primary lead investigator

Christina Chambers

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/10/2015

Actual: 20/11/2015

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**Study start date**

Planned: 30/10/2015

Actual: 01/12/2015

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**Data analysis start date**

Planned: 01/12/2022

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**Date of final study report**

Planned: 30/06/2023

Actual: 02/06/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Takeda

## Study protocol

[Vedolizumab-5001 Protocol Version 1 2015-10-05.pdf](#)(690.15 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)?**

Non-EU RMP only

## Methodological aspects

### Study type

**Study topic:**

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

Drug utilisation

**Main study objective:**

The primary objective of the study is to assess the prevalence of major structural birth defects in infants of women with UC or CD exposed to vedolizumab during pregnancy, compared to women with UC or CD exposed to other biologic agents.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine**

ENTYVIO

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

VEDOLIZUMAB

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**Anatomical Therapeutic Chemical (ATC) code**

(L04AA33) vedolizumab

vedolizumab

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**Medical condition to be studied**

Colitis ulcerative

Crohn's disease

## 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**

300

## Study design details

**Outcomes**

Primary outcome included the major structural defects (either cosmetic or functional significance to the child) identified after infant's birth up to 1 year of age. Secondary outcome included the minor structural defects (neither cosmetic or functional significance to the child) identified through dysmorphology examination after infant's birth up to 1 year of age.

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## Data analysis plan

Primary analysis between the vedolizumab-exposed group and the other biologic agents-exposed group will use Fisher exact test for univariate comparisons and logistic regression for multivariate analysis with adjustment for confounders.

## Documents

### Study results

[Final OTIS Entyvio Analysis Report\\_02June2023.pdf\(161.9 KB\)](#)

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## Data management

## Data sources

### Data sources (types)

[Disease registry](#)

[Electronic healthcare records \(EHR\)](#)

[Other](#)

[Pregnancy registry](#)

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### Data sources (types), other

Prospective patient-based data collection, Exposure 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