# Vedolizumab-5014: Incidence of adverse events of special interest in patients with Crohn’s disease or ulcerative colitis treated with Entyvio as compared to anti-TNF-alpha agents

**First published:** 09/02/2017

**Last updated:** 02/04/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS14135

**Study ID**

44109

**DARWIN EU® study**

No

**Study countries**

United States

**Study description**

Study was withdrawn prior to data collection - The drug being tested in this study is called Entyvio (vedolizumab). Vedolizumab was launched in the United States in June 2014 for treatment of people who have crohn's disease (CD) and ulcerative colitis (UC). This study will look at the real-world evidence on utilization and safety of Entyvio in routine clinical practice. The study will enroll approximately 1250 participants. The data will be taken from the Optum health insurance claims database from May 1, 2000. All participants who received one of the two treatments where included in this study: - Vedolizumab infusion - Anti-tumor necrosis factor-alpha (TNF-alpha) agent The overall time to extract the data from the Optum claims database is approximately 4 years. Participants in both groups will be followed from index date to the occurrence of last data collected, disenrollment of membership, switching to another biologic product, or date of death, whichever date comes first.

---

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Takeda

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

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

**Institution**

# Contact details

**Study institution contact**

Huifang Liang trialdisclosures@takeda.com

Study contact

trialdisclosures@takeda.com

**Primary lead investigator**

Huifang Liang

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 11/09/2015

Actual: 11/09/2015

---

**Study start date**

Planned: 30/11/2015

Actual: 30/11/2015

---

**Data analysis start date**

Planned: 30/11/2015

Actual: 30/11/2015

---

**Date of final study report**

Planned: 01/06/2020

Actual: 30/11/2015

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Takeda

## Regulatory

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

No

---

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

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Human medicinal product

Disease /health condition

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

---

**Main study objective:**

To describe clinical characteristics and treatment history of participants initiating Entyvio and to quantify the incidence rates of adverse events in UC or CD participants who initiated Entyvio or an anti-TNF-alpha agent.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

VEDOLIZUMAB

ADALIMUMAB

CERTOLIZUMAB

GOLIMUMAB

INFLIXIMAB

---

**Medical condition to be studied**

Colitis ulcerative

Crohn's disease

## Population studied

**Short description of the study population**

All participants with UC or CD who initiated Entyvio (Vedolizumab infusion) or an anti-TNF-alpha agent as first line or second line biologic therapy on or after 1 June 2014. Data was collected from Optum health insurance claims database from May 1, 2000.

---

**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)

---

**Special population of interest**

Other

---

**Special population of interest, other**

Patients with Crohn's disease, Colitis ulcerative

---

**Estimated number of subjects**

1.250

# Study design details

**Outcomes**

Percentage of Participants with Adverse Events of Special Interest

---

**Data analysis plan**

Descriptive analysis used to describe clinical characteristics and treatment history of participants. Incidence rates (and 95 percent % confidence interval CIs) of outcomes will be calculated as cumulative incidence and as incidence rate per 100 person years. Rates will be stratified into Entyvio or anti-TNF-alpha agent initiated as 1st or 2nd line biologic therapy. Mean and standard deviations, medians and ranges will be generated for continuous variables. Participant counts, proportions and Chi-square test will be used for categorical variables. For continuous variables, Student's t test will be used to test means between groups (CD vs UC, Entyvio vs anti-TNF-alpha), and Rank sums Wilcoxon two-sample median test will be used to test medians between groups. Two-sample independent tests will be used for group comparisons, participants who had both Entyvio and anti-TNF-alpha observation periods will be considered Entyvio participants only for baseline characteristics.

# 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)**

Administrative healthcare records (e.g., claims)

## 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