

# An observational post-authorization safety study to describe the safety of ustekinumab and other treatments of ulcerative colitis in a cohort of patients with ulcerative colitis using the French Nationwide claims database (SNDS) France

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**Last updated:** 26/11/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS36129

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### Study ID

45589

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### DARWIN EU® study

No

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### Study countries


## Study status

Ongoing

## Research institutions and networks

### Institutions

#### University of Bordeaux

 France

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**Institution**

**Educational Institution**

## Contact details

### Study institution contact

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**Study contact**

[aazzabi@its.jnj.com](mailto:aazzabi@its.jnj.com)

### Primary lead investigator

Patrick Blin

**Primary lead investigator**

# Study timelines

## **Date when funding contract was signed**

Actual: 14/04/2020

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## **Study start date**

Planned: 31/12/2022

Actual: 30/01/2023

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## **Date of interim report, if expected**

Planned: 30/11/2025

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## **Date of final study report**

Planned: 31/12/2027

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Janssen-Cilag International, NV

# 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:**

Other

**If 'other', further details on the scope of the study**

Long term safety profile of ustekinumab for UC, as measured by incidence of malignancies, infections (serious infections, opportunistic infections, and tuberculosis) and VTE.

**Main study objective:**

The primary study objective is to describe the long-term safety of ustekinumab for UC, as measured by incidence of malignancies, infections (serious infections, serious opportunistic infections and tuberculosis), VTE, MACE and all-cause mortality The secondary study objective is to compare the long-

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

## **Medical condition to be studied**

Colitis ulcerative

## Population studied

### **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)

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### **Estimated number of subjects**

6667

## Study design details

### **Outcomes**

Malignancies, infections and VTEs at 3-year and 5-year of follow-up: Incidence rate expressed per 1 000 patient-year in each cohort, Estimation of the cumulative incidence of each outcome in each cohort Comparison of incidence of each study outcome defined above between: ustekinumab and primary comparator, ustekinumab and secondary comparator

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### **Data analysis plan**

Analyses will be conducted for each outcome and will include descriptive analyses, comparative analyses, and any relevant sensitivity analyses for each

study cohort. Population description, comparative and sensitivity analyses will be performed at 3-year and 5-year follow-up

## 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 source(s), other**

SNIIRAMSND S France

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### **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

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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