

# An Observational Postauthorization Safety Study To Describe The Safety Of Ustekinumab and Other Biologic Treatments in a Cohort of Patients With Ulcerative Colitis or Crohn's Disease Using Compulsory Swedish Nationwide Healthcare Registers and the Independent Swedish National Quality Register for Inflammatory Bowel Disease (SWIBREG) (Stelara UC/CD PASS (SWIBREG))

**First published:** 04/01/2022

**Last updated:** 11/08/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS44885

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### Study ID

45899

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## **DARWIN EU® study**

No

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### **Study countries**

 Sweden

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### **Study description**

Observational study, all drugs are prescribed (and dispensed) or administered in hospital and hospitalizations or follow-up visits registered as a part of routine medical practice.

Primary objective: evaluate the long-term safety of ustekinumab (incidence of malignancies, infections (serious infections, opportunistic infections, and tuberculosis) and venous thromboembolic events), in patients treated with ustekinumab for Crohn's disease (CD) and Ulcerative Colitis (UC).

Secondary objective: compare long-term safety in CD and UC patients treated with ustekinumab and patients treated with other IBD (CD and UC) disease therapies, including TNF-alpha inhibiting (TNFi) agents or anti-integrins.

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### **Study status**

Ongoing

## **Research institutions and networks**

### **Institutions**

**Centre for Pharmacoepidemiology, Karolinska  
Institutet (CPE-KI)**

 Sweden

**First published:** 24/03/2010

**Last updated:** 23/04/2024

**Institution**

**Educational Institution**

**Laboratory/Research/Testing facility**

**Not-for-profit**

**ENCePP partner**

## Contact details

### Study institution contact

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**Study contact**

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### Primary lead investigator

Ola Olen

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Planned: 01/02/2022

Actual: 20/06/2022

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### Study start date

Planned: 15/02/2023

Actual: 13/02/2023

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## **Date of final study report**

Planned: 31/03/2028

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Janssen Pharmaceutical

## 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 topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Main study objective:**

To describe the long-term safety of ustekinumab for UC and/or CD, as measured by incidence of malignancies, infections (serious infections, opportunistic infections, and tuberculosis TB), venous thromboembolism (VTE), major adverse cardiac events (MACE), and all-cause mortality.

## Study drug and medical condition

**Medicinal product name**

STELARA

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**Medicinal product name, other**

ustekinumab

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

USTEKINUMAB

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**Anatomical Therapeutic Chemical (ATC) code**

(L04AC05) ustekinumab

ustekinumab

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**Medical condition to be studied**

Colitis ulcerative

Crohn's disease

## Population studied

## Age groups

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
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## Estimated number of subjects

8000

# Study design details

## Data analysis plan

The event rate of safety outcomes will be estimated for each cohort for patients using ustekinumab, TNFi, or anti-integrins.

The analysis will be performed to compare the following outcomes:

- incidence rate of malignancies
- incidence rate of infections (incl. serious infections, opportunistic infections, TB)
- incidence rate of VTEs. Incidence rates per 1,000 person-years of follow-up.

For malignancy outcomes, patients will be assigned to treatment cohorts based on a hierarchical order of exposure:

- STELARA (ustekinumab)
- TNFi biologics
- Integrin Inhibitors. The final report, as well as the interim reports, will include data on the number of patients who have entered the study in each of the treatment cohorts, cumulative follow-up time accrued in each cohort, and counts of each study outcome of interest tabulated by exposure status at cohort entry. The analysis will be performed separately for patients with CD, patients with UC and patients with IBD (UC or CD).

## 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**

Swedish Cancer Register Sweden, Total Population Register Sweden, National Patient Register (NPR) Sweden, Infectious Disease Register (IDR) Sweden, Prescribed Drug Register (PDR) Sweden

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### **Data sources (types)**

[Disease registry](#)

[Other](#)

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### **Data sources (types), other**

Case-control surveillance database

## 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