

# An Observational Post-authorization Safety Study to Describe the Safety of Ustekinumab and Other Crohn's Disease Treatments in a Cohort of Patients With Crohn's Disease

**First published:** 29/01/2018

**Last updated:** 04/09/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS21954

---

### Study ID

48842

---

### DARWIN EU® study

No

---

### Study countries

 Belgium

 Denmark

-  France
  -  Germany
  -  Greece
  -  Hungary
  -  Ireland
  -  Israel
  -  Italy
  -  Netherlands
  -  Poland
  -  Portugal
  -  Spain
  -  Sweden
  -  United Kingdom
- 

## **Study description**

This is an observational, post-authorization safety study to describe the safety profile of adult patients with CD enrolled into the I-CARE study - an independent, ongoing, prospective, observational, multicenter cohort study. This study will include patients who receive ustekinumab treatment and those receiving other CD treatments within routine clinical practice, using data collected in the I-CARE study. The source population is derived from the I-CARE study, enrolling patients with CD, ulcerative colitis or IBD at sites in 16 countries across Europe. This study will focus primarily on patients enrolled into I-CARE who are being treated for CD with ustekinumab. Patients enrolled into I CARE will complete an electronic-diary on a monthly basis and an e-PRO questionnaire on a yearly basis. Additionally, a gastroenterologist will complete an annual summary at least once yearly. Patients enrolled in the study will be observed for 3 years. The final patient population of the I-CARE study will be at least 10,000 IBD patients split into 6 patient groups, with approximately 2,000 patients in the ustekinumab cohort of CD patients.

---

## Study status

Finalised

## Research institutions and networks

### Institutions

Groupe d'Étude Thérapeutique des Affections Inflammatoires du Tube Digestif (GETAID)

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

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

Institution

### Networks

Groupe d'Étude Thérapeutique des Affections Inflammatoires Digestives (G.E.T.A.I.D.)

## Contact details

### Study institution contact

Ahlem Azzabi RA-RNDUS-CInclTrlsEU@its.jnj.com

Study contact

[RA-RNDUS-CInclTrlsEU@its.jnj.com](mailto:RA-RNDUS-CInclTrlsEU@its.jnj.com)

## Primary lead investigator

Ahlem Azzabi

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 10/12/2017

Actual: 20/11/2017

---

### Study start date

Planned: 31/12/2019

Actual: 15/12/2017

---

### Date of final study report

Planned: 30/09/2023

Actual: 26/09/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Janssen Pharmaceutica NV

## Study protocol

[Redacted Protocol RRA-20745.pdf](#) (2.21 MB)

## Regulatory

## Was the study required by a regulatory body?

Yes

---

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

---

#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

#### **Main study objective:**

Evaluate long-term safety of ustekinumab, as measured by the occurrence of malignancies, serious infections & VTEs associated with hospitalization, in adult patients with CD treated with ustekinumab, Evaluate risk factors for VTEs, infections and malignancies, Estimate long-term safety of adult patients with CD between users of ustekinumab and users of other CD therapies.

## Study Design

## **Non-interventional study design**

Cohort

Other

---

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

Secondary data analysis from prospective cohort study

## Study drug and medical condition

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

USTEKINUMAB

---

### **Medical condition to be studied**

Crohn's disease

## 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)
- 

### **Estimated number of subjects**

5115

## Study design details

## **Outcomes**

Malignancies, Serious infections (including opportunistic infections and tuberculosis TB), Events of VTE recorded with/during hospitalization.

---

## **Data analysis plan**

This study will use data collected from a cohort of patients enrolled into I-CARE and who are treated with ustekinumab or other treatments for CD. The event rate of safety outcomes will be estimated for each cohort. Adverse events and serious adverse events will also be summarized. Where possible, the cumulative event rate outcomes will be estimated using time-to-event analyses, overall by cohorts and then in stratified analyses. Stratification factors (as measured at study entry) will be evaluated one at a time. For each safety outcome, risk will be compared between ustekinumab and comparators using survival analysis. Users of ustekinumab will be compared with users of anti-TNF agents and with users of immunomodulators. Study exposures will be treated as time-dependent variables. Hazard ratios will be used to estimate relative risk. A propensity score (PS) analysis will be performed to assess in an explorative manner the 'treatment effect' when adjusting for the potential confounders

## Documents

### **Study results**

[REDACTED\\_CSR-Body-RRA-20745-1071569\\_1199308.pdf](#) (685.61 KB)

---

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**

GETAID France

---

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

[Disease registry](#)

[Other](#)

---

### **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

---

### **Check completeness**

Unknown

---

**Check stability**

Unknown

---

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No