

# Drug Utilization Study Evaluating Additional Risk Minimisation Measures for Upadacitinib in the Treatment of Ulcerative Colitis in Europe

**First published:** 16/01/2024

**Last updated:** 12/05/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS107885

---

### Study ID

199004

---

### DARWIN EU® study

No

---

### Study countries

Denmark

Spain

Sweden

---

## **Study description**

The study aims to evaluate the use of upadacitinib in patients with ulcerative colitis (UC) in routine clinical care in Denmark, Sweden, and Spain.

The study objectives are:

1. To describe the baseline characteristics of patients with UC who are new users of upadacitinib.
2. To the extent measurable, evaluate healthcare utilization in routine clinical care as indicator of physician adherence to the additional risk minimisation measures (aRMMs) among patients with UC who are new users of upadacitinib, by:
  - a) Quantifying the compliance to recommendations for posology (average daily dose) and duration of use;
  - b) Quantifying the compliance to recommendations for the use among patients who have risk factors for gastrointestinal (GI) perforation, malignancy, major adverse cardiovascular events (MACE), venous thromboembolic events (VTE), and serious infections;
  - c) Quantifying the compliance to the recommendations for the use among patients aged 65 years and older;
  - d) Quantifying the compliance to the recommendations for contraindicated use including pregnancy and active tuberculosis (TB);
  - e) Quantifying the compliance to recommendations for patient screening and laboratory monitoring prior to and during upadacitinib treatment (Denmark and Spain only).
3. To describe the changes in the utilization of upadacitinib following the implementation of revised aRMMs from the Article 20 referral procedure (Sweden only), specifically:
  - a) Describe the use of upadacitinib among patients with risk factors for VTE, MACE, malignancy, and serious infections;
  - b) Describe the use of upadacitinib among patients aged 65 years and older;

c) Describe the use of higher maintenance dose of upadacitinib 30 mg.

---

### 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

#### Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark

**First published:** 20/07/2021

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

**Institution**

Educational Institution

ENCePP partner

## RTI Health Solutions (RTI-HS)

- France
- Spain
- Sweden
- United Kingdom
- United Kingdom (Northern Ireland)
- United States

**First published:** 21/04/2010

**Last updated:** 13/03/2025

**Institution**

**Not-for-profit**

**ENCePP partner**

## Contact details

### Study institution contact

Karin Gembert [karin.gembert@ki.se](mailto:karin.gembert@ki.se)

**Study contact**

[karin.gembert@ki.se](mailto:karin.gembert@ki.se)

### Primary lead investigator

Johan Reutfors

**Primary lead investigator**

## Study timelines

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

Actual: 25/08/2022

---

## **Study start date**

Planned: 22/06/2023

Actual: 14/12/2023

---

## **Data analysis start date**

Planned: 31/03/2027

---

## **Date of final study report**

Planned: 30/09/2027

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

AbbVie

## Study protocol

[p24344-protocol-pmos-v1.2\\_10Nov2023\\_Redacted 2\\_21Jun2024.pdf](#) (12.27 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)

## Other study registration identification numbers and links

P24-344

### Methodological aspects

#### Study type

#### Study type list

**Study topic:**

Human medicinal product

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Drug utilisation

**Main study objective:**

To describe the baseline characteristics and, to the extent measurable, evaluate healthcare utilization in routine clinical care as indicator of physician adherence to the aRMMs among patients with UC who are new users of upadacitinib.

To describe the changes in the utilization of upadacitinib following the implementation of revised aRMMs from the Article 20 referral procedure (in

Sweden only).

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Medicinal product name**

RINVOQ

---

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

UPADACITINIB

---

### **Anatomical Therapeutic Chemical (ATC) code**

(L04AF03) upadacitinib

upadacitinib

---

### **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)
- 

### **Estimated number of subjects**

2000

## Study design details

### **Outcomes**

Indicators of physician adherence to the additional risk minimisation measures related to malignancy, MACE, GI perforation, VTE, serious infections, contraindication and posology, Baseline characteristics

---

### **Data analysis plan**

All analyses will be descriptive; no statistical tests will be performed. Proportions of the outcome variables will be assessed prior to upadacitinib initiation, at upadacitinib initiation and during follow-up, depending on the outcome variable being reported.

## 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.

This study has been awarded the ENCePP seal

### **Conflicts of interest of investigators**

[KI-CPE-DeclarationofInterests-Annex5\\_P24-344.pdf](#) (322.59 KB)

[AU-DCE-DeclarationofInterests-Annex5\\_P24-344.pdf](#) (171.24 KB)

[RTI-HS-DeclarationofInterests-Annex5\\_P24-344.pdf](#) (217.7 KB)

[DeclarationofInterests-Annex5\\_MBarreiro P24-344.pdf](#) (166.55 KB)

---

### **Composition of steering group and observers**

[EUPAS107885-108467.pdf](#) (60.64 KB)

---

### **Signed code of conduct**

[ENCePPCoCAnnex3\\_DeclarationofcompliancewiththeENCePPCodeofConduct\\_JR.pdf](#)

(57.54 KB)

---

### **Signed code of conduct checklist**

[ENCePPCoCAnnex2\\_ChecklistofCodeofConduct\\_upa UC RMM\\_JR.pdf](#) (549.14 KB)

---

### **Signed checklist for study protocols**

[Signed ENCePP checklist protocol\\_upa UC RMM-05sep2023\\_JR.pdf](#) (146.61 KB)

---

## Data sources

### **Data source(s)**

Danish registries (access/analysis)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

---

**Data source(s), other**

- SWIBREG, Sweden
  - SMINET, Sweden
  - Swedish National Registers
  - ENEIDA, Spain
- 

**Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

[Disease registry](#)

[Other](#)

---

**Data sources (types), other**

Pharmacy dispensing records, quality register, medical chart abstraction

## 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