

# Drug Utilization Study Evaluating Additional Risk Minimization Measures for Upadacitinib in the Treatment of Atopic Dermatitis in Europe

**First published:** 25/06/2024

**Last updated:** 23/05/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS49233

---

### Study ID

1000000166

---

### DARWIN EU® study

No

---

### Study countries

- Denmark
- Germany
- Spain

## **Study description**

The study aims to evaluate the use of upadacitinib (RINVOQ®) in individuals with AD in routine clinical care in Denmark, Germany, Spain, and Sweden. The study objectives are:

1. To describe the baseline characteristics of individuals with AD who are new users of upadacitinib.
  2. To the extent measurable, evaluate healthcare utilization in routine clinical care as an indicator of physician adherence to the aRMMs among individuals with AD who are new users of upadacitinib, by:
    - a. Quantifying the compliance to recommendations for posology (average daily dose) and by describing the duration of use.
    - b. Quantifying the compliance to recommendations for the use among individuals who have risk factors for GI perforation, serious infections, malignancy, MACE, and VTE.
    - 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 TB.
    - e. Quantifying the compliance to recommendations for patient screening and laboratory monitoring prior to and during upadacitinib treatment (Denmark, Germany, 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, 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 upadacitinib 30 mg.
-

## Study status

Ongoing

## Research institutions and networks

### Institutions

#### Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

**First published:** 29/03/2010

**Last updated:** 26/02/2024

Institution

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

#### 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

Fundació Institut Universitari per a la Recerca a  
l'Atenció Primària de Salut Jordi Gol i Gurina,  
IDIAPJGol

Spain

**First published:** 05/10/2012

**Last updated:** 23/05/2025

**Institution**

Educational Institution

Laboratory/Research/Testing facility

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

Planned: 15/11/2021

Actual: 08/12/2021

---

### Study start date

Planned: 25/04/2024

Actual: 25/04/2024

---

### Data analysis start date

Planned: 30/06/2024

---

### Date of final study report

Planned: 30/09/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

AbbVie

## Study protocol

[p21825-protocol-pmos-v3.2\\_Redacted.pdf](#) (2.04 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

P21-825

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Human medicinal product

---

#### **Study type:**

Non-interventional study

---

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

Drug utilisation

#### **Data collection methods:**

**Study design:**

The study is a drug utilization, descriptive, non-interventional, population-based, cohort study of new users of upadacitinib (RINVOQ®) for the treatment of AD identified in electronic healthcare data from four European countries: Denmark, Germany, Spain, and Sweden.

**Main study objective:**

The objectives are to describe the baseline characteristics of individuals with AD who are new users of upadacitinib, and to the extent measurable, evaluate healthcare utilization in routine clinical care as an indicator of physician adherence to the aRMMs among individuals with AD 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.

## 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**

Dermatitis atopic

## Population studied

**Short description of the study population**

The study population consists of all individuals with AD registered in the databases in the four countries who are treated with upadacitinib. Each individual will be followed from the initiation of upadacitinib to the end of the study period (i.e., 31 December 2024), study withdrawal, or death.

---

**Age groups**

- Adolescents (12 to < 18 years)
  - Adults (18 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
- 

**Special population of interest**

Hepatic impaired

Pregnant women

Renal impaired

---

**Estimated number of subjects**

## Study design details

### Setting

The study is based on electronic healthcare data from Denmark, Germany, Spain, and Sweden covering populations of approximately 5.8 million, 25 million, 5.8 million, and 10.2 million people, respectively.

---

### Outcomes

Indicator of physician adherence to the additional risk minimisation measures related to malignancy, MACE, GI perforation, VTE, serious and opportunistic infections including HZ, contraindications (pregnancy, and active TB) and posology.

To describe the baseline characteristics of new users of upadacitinib.

---

### Data analysis plan

This will be a descriptive study. Upon upadacitinib initiation, baseline characteristics of individuals will be assessed. Proportions of the aRMM outcome variables will be assessed prior to upadacitinib initiation, at upadacitinib initiation and during continuous treatment of upadacitinib, depending on the outcome variable being reported.

The proportion of the outcome variables will be calculated as the number of individuals for each specific outcome variable over the total number of individuals considered for that specific outcome.

Utilization of upadacitinib will be stratified by the time period before and after the implementation of the revised aRMMs from the Article 20 referral procedure as well as by Coronavirus disease 2019 (COVID-19) pandemic time periods (COVID-19 pandemic and non-COVID-19 pandemic).

## Data management

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**

[Dols combined\\_upa AD RMM.pdf](#) (2.56 MB)

---

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

[Composition of Steering Group and Observers.pdf](#) (60.64 KB)

---

### **Signed code of conduct**

[Annex3\\_Declaration-Upa AD RMM\\_signed.pdf](#) (241.69 KB)

---

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

[Annex2\\_Checklist\\_Upa AD RMM\\_signed.pdf](#) (1.58 MB)

---

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

[Signed ENCePP checklist for Upa AD RMM v1.0 Study Protocol.pdf](#) (128.96 KB)

---

## Data sources

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

Sweden National Cancer Register / Cancerregistret

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Danish registries (access/analysis)

---

### **Data source(s), other**

The Swedish National Patient register

The Swedish Cause of Death Register

Swedish Medical Birth Register

SMINET

---

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

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

[Disease registry](#)

[Laboratory tests and analyses](#)

[Population registry](#)

## 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