

# Long-term comparative safety cohort studies of upadacitinib (Rinvoq™) use for the treatment of RA in Europe

**First published:** 12/02/2021

**Last updated:** 02/07/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS39217

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### Study ID

47968

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### DARWIN EU® study

No

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### Study countries

- Denmark
- Germany
- Spain
- Sweden

United Kingdom (Northern Ireland)

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### Study description

The purpose of this study is to evaluate and characterise the important identified and potential risks of upadacitinib (Rinvoq™) and missing information on the safety of upadacitinib, as described in the European Union (EU) Risk Management Plan (RMP) for Rinvoq™ (upadacitinib). This study aims to evaluate the long-term safety of upadacitinib among patients with RA receiving routine clinical care.

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### Study status

Ongoing

## Research institutions and networks

### Institutions

Aarhus University & Aarhus University Hospital  
DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark

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**Institution**

**Educational Institution**

**ENCePP partner**

### Contact details

### **Study institution contact**

Clinical Trial AbbVie CT.Disclosures@abbvie.com

Study contact

[CT.Disclosures@abbvie.com](mailto:CT.Disclosures@abbvie.com)

### **Primary lead investigator**

Clinical Trial AbbVie

Primary lead investigator

## Study timelines

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

Planned: 25/11/2020

Actual: 25/11/2020

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### **Study start date**

Planned: 01/01/2020

Actual: 15/06/2021

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### **Date of final study report**

Planned: 31/03/2030

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

AbbVie

## Study protocol

[p19150-protocol abstract-pmos\\_Redacted.pdf](#) (218.99 KB)

[P19150-protocol-pmos-v3-Abstract\\_Redacted.pdf](#) (279.11 KB)

## 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)

## Other study registration identification numbers and links

P19-150

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

The purpose of this study is to evaluate and characterise the important identified and potential risks of upadacitinib (Rinvoq™) and missing information on the safety of upadacitinib, as described in the European Union (EU) Risk Management Plan (RMP) for Rinvoq™ (upadacitinib). This study aims to evaluate the long-term safety of upadacitinib among patients with RA receiving routine clinical care.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

RINVOQ

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**Medical condition to be studied**

Rheumatoid arthritis

## 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**

12000

# Study design details

## **Outcomes**

To describe and compare (when possible) the incidence rates of the following important risks: serious and opportunistic infections (including herpes zoster and tuberculosis TB), malignancies, major adverse cardiovascular events (MACE), venous thromboembolism (VTE), mortality, gastrointestinal (GI) perforations, and liver injury (including drug-induced liver injury DILI. To describe the incidence rates among patients with missing information on the safety of upadacitinib, including the very elderly ( $\geq 75$  years of age), and when data are available, in patients with moderate hepatic impairment, patients with severe renal impairment, and patients with evidence of chronic infection with hepatitis B or hepatitis C.

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## **Data analysis plan**

Analyses will be conducted separately for each outcome in each registry and will include descriptive analyses of baseline characteristics and cumulative rates of study endpoints (i.e. events of special interest or serious adverse events SAEs, depending on registry) for each exposure cohort. Comparative

analyses will be performed to evaluate whether upadacitinib treatment is associated with an increased risk of outcomes of interest relative to control cohorts.

## 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)

British Society for Rheumatology Biologics Register for Rheumatoid Arthritis

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### Data source(s), other

BSRBR - Rheumatic and Musculoskeletal conditions

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### Data sources (types)

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

[Disease registry](#)

[Other](#)

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### 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

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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