

# Non-Interventional Study to Review the Changes of Depression after First-Year of Tofacitinib Treatment in Rheumatoid Arthritis (XELJANZ®)

**First published:** 01/04/2021

**Last updated:** 05/02/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS40263

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### Study ID

48626

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### DARWIN EU® study

No

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### Study countries

 Czechia

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### Study description

This study is to describe and evaluate the changes of depression level within 12 months from the start of Tofacitinib therapy in patients with Rheumatoid arthritis

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### Study status

Finalised

## Research institutions and networks

### Institutions

[Pfizer](#)

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**Institution**

[MEDICAL PLUS, s.r.o. Uherské Hradiště,](#)  
[Revmatologická ambulance Ostrava,](#)  
[Thomayerova nemocnice Prague, Revmatologický](#)  
[ústav Prague, RHEUMA s.r.o. Břeclav, BORMED,](#)  
[spol. s r.o. Ostrava-Třebovice, Revmatologie s.r.o.](#)  
[Brno, Value Outcomes s.r.o](#)

### Contact details

### **Study institution contact**

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Study contact

[Dana.Vidimova@pfizer.com](mailto:Dana.Vidimova@pfizer.com)

### **Primary lead investigator**

Elke Binder

Primary lead investigator

## Study timelines

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

Planned: 01/09/2019

Actual: 19/09/2019

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### **Study start date**

Planned: 01/06/2020

Actual: 23/07/2020

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### **Data analysis start date**

Planned: 29/02/2024

Actual: 07/02/2024

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

Planned: 07/01/2025

Actual: 09/12/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

[A3921330 Final Protocol 02 April 2019\\_Public.pdf](#) (7.96 MB)

[A3921330 Non Interventional Study Protocol\\_Amendment 1 V2\\_clean\\_18Jun2021\\_Public.pdf](#) (2.53 MB)

## Regulatory

**Was the study required by a regulatory body?**

No

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

Not applicable

## Methodological aspects

Study type

Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Main study objective:**

To describe and evaluate the changes of depression level within 12 months from the start of Tofacitinib therapy.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Single arm, prospective

## Study drug and medical condition

**Medicinal product name**

[XELJANZ](#)

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

TOFACITINIB

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**Medical condition to be studied**

Rheumatoid arthritis

Depression

Insomnia

Anxiety

Arthralgia

## 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**

73

## Study design details

### **Outcomes**

- To find out if treatment by Tofacitinib reduces the depression by at least 10% during 12 months.
  - To describe and evaluate the level and changes of pain, anxiety and insomnia in patients with RA.
  - To describe the safety and effectiveness of Tofacitinib for the treatment of rheumatoid arthritis.
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### **Data analysis plan**

Detailed methodology for summary and statistical analyses of data collected in this study will be documented in a Statistical Analysis Plan (SAP). Unless

specified otherwise, continuous variables will be summarized using descriptive statistics (n, mean, SD, median, min, max) and discrete variables will be summarized using counts and percentages. To access drop-out, study flow-chart (patient disposition) between visits will be preset.

## Documents

### Study report

[A3921330\\_NI STUDY REPORT\\_03Dec2024\\_Redacted.pdf](#) (3.77 MB)

[A3921330\\_NI STUDY REPORT ABSTRACT\\_03Dec2024\\_Redacted.pdf](#) (237.71 KB)

### Study, other information

[A3921330\\_Abstract\\_18 June 2021.pdf](#) (1.27 MB)

## 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 sources (types)

[Electronic healthcare records \(EHR\)](#)

## 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