

# Canadian Non-Interventional Study of Xeljanz in Rheumatoid Arthritis (CANTORAL)

**First published:** 26/10/2017

**Last updated:** 22/02/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS21413

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### Study ID

49540

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### DARWIN EU® study

No

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### Study countries

 Canada

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### Study description

The study will describe the baseline, characteristics of Canadian RA patients initiating tofacitinib in clinical practice and subsequently assessing disease activity, patient reported outcomes, and persistence of response.

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## Study status

Finalised

## Research institutions and networks

### Institutions

Pfizer

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Institution

Multiple centres: 50 centres are involved in the study, Adachi Medicine Professional Corp, Hamilton, Canada, Manna Research Inc, Burlington, Canada, Nexus Clinical Research, St John's, Canada, Clinical Research and Arthritis Centre, Windsor, Canada, Oshawa Clinic, Oshawa, Canada, Clinique Medicale Viau, Saint-Leonard, Canada

### Networks

## Contact details

### Study institution contact

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Study contact

[Cristina.Sciortino@pfizer.com](mailto:Cristina.Sciortino@pfizer.com)

### Primary lead investigator

Edith Owens

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/07/2017

Actual: 12/07/2017

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### Study start date

Planned: 15/10/2017

Actual: 31/10/2017

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### Data analysis start date

Planned: 30/11/2019

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### Date of final study report

Planned: 30/05/2023

Actual: 09/05/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer Inc

## Study protocol

[A3921280\\_FINAL PROTOCOL V1.1\\_02OCT2017.pdf](#) (378.03 KB)

[A3921280 Protocol Amendment 4 19Jan2022.pdf](#) (2.11 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 topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

1) To describe the profile of RA patients initiating treatment with tofacitinib in the Canadian real - world/clinical setting. 2) To describe the clinical effectiveness of tofacitinib over time in patients with moderate to severe RA in the real-world/clinical setting.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Observational, multi-centre study

## Study drug and medical condition

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

(L04AA29) tofacitinib

tofacitinib

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## **Medical condition to be studied**

Rheumatoid arthritis

## **Population studied**

### **Short description of the study population**

Patients aged 18 years or older diagnosed with rheumatoid arthritis (RA) treated with tofacitinib.

Inclusion Criteria:

1. Adult patients, at least 18 years of age or older at the time of recruitment.
2. Diagnosis with RA as per the revised 1987 American College of Rheumatology (ACR) criteria or 2010 ACR/EULAR criteria.
3. Patients for whom the treating physician has made the decision to commence tofacitinib treatment in accordance with the Canadian Product Monograph.
4. Initiation of treatment with tofacitinib within 28 days from study enrolment.
5. Acceptance for patients to participate in the study and the signing of the informed consent.

Exclusion Criteria:

1. Patients who do not have the ability answer the questionnaires by themselves or who have any kind of disorder that may affect their answers.
2. Patients diagnosed with autoimmune rheumatic diseases other than RA.
3. Cannot or will not sign informed consent.

4. Active participation or enrollment in an interventional trial.
  5. Previous experience with tofacitinib through either a clinical trial or previous treatment.
  6. Is not expected to be available for follow up assessments as required for adequate management.
  7. According to the judgment of the physician will not be able to participate in the study including the presence of any condition that, in the opinion of the treating physician, prohibits the patient from participating in the study or obscures the assessment of the treatment of RA.
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### **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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### **Special population of interest**

Other

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### **Special population of interest, other**

Patients with rheumatoid arthritis

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### **Estimated number of subjects**

500

## **Study design details**

### **Outcomes**

The primary outcome variable of the study will be the Clinical Disease Assessment Index (CDAI). Tender Joint Count, Swollen Joint Count, DAS28, SDAI, Physician Global Assessment of Disease Activity, Patient Global Assessment of Disease Activity, Patient Subjective Assessment of Pain, Health Assessment Questionnaire Disability Index, Routine Assessment of Patient Index Data-3, EuroQol, Work Productivity and Activity Impairment: Treatment Satisfaction, Fatigue, Health Resource Utilization

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### **Data analysis plan**

The analyses conducted for the study will be predominantly descriptive with several associations assessed with bivariate and multivariate methods.

However, given that there are no specific a-priori defined hypotheses being tested, there is no need for multiplicity correction for the number of associations tested and the number of outcomes assessed. Hence any p-values presented should be considered as descriptive statistics themselves, and, there will be no declarations of statistical significance. The analyses will be conducted on observed cases without imputation for missing data in order to preserve the observational nature of the study. The Full Analysis Set (FAS) will be comprised of all enrolled patients providing consent to participate in the study.

Nevertheless, the use of mixed effects models will help to compensate for missing observations, patient attrition and unequal time intervals between assessments.

## **Documents**

### **Study results**

[A3921280 Non Interventional Study Report Abstract 01 May 2023\\_Redacted.pdf](#)  
(1.91 MB)

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### **Study report**

[A3921280 Non Interventional Study Report 01 May 2023\\_Redacted \(2\).pdf](#) (5.86 MB)

### **Study, other information**

[A3921280\\_NON-INTERVENTIONAL STUDY ABSTRACT v4.0\\_19Jan2022.pdf](#) (1.76 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)**

[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

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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