

# Depicting real-life treatment journeys for patients affected with an immune-inflammatory condition and treated with methotrexate

**First published:** 17/05/2024

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Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000159

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### Study ID

1000000159

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### DARWIN EU® study

No

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### Study countries

 France

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### Study status

Ongoing

## Contact details

### Study institution contact

Vincent Bouget [vincent.bouget@scientalab.com](mailto:vincent.bouget@scientalab.com)

Study contact

[vincent.bouget@scientalab.com](mailto:vincent.bouget@scientalab.com)

### Primary lead investigator

Vincent Bouget

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 27/04/2023

Actual: 27/04/2023

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### Study start date

Actual: 27/04/2023

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### Date of final study report

Planned: 30/09/2026

## Sources of funding

- Other
- Pharmaceutical company and other private sector

## 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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#### **Main study objective:**

The main objective of this study is to provide a depiction of patient-level treatment journeys of autoimmune patients.

### Study Design

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

Cross-sectional

### Study drug and medical condition

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

METHOTREXATE

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

(L04AX03) methotrexate

methotrexate

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## **Additional medical condition(s)**

Immune-inflammatory condition

## **Population studied**

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

Patient will be included if they are suspected to be affected by one of the following condition: rheumatoid arthritis, psoriasis, psoriatic arthritis, systemic lupus erythematosus and juvenile idiopathic arthritis. In addition, patients have to receive at least one methotrexate injection.

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### **Age groups**

- **Paediatric Population (< 18 years)**

- Preterm newborn infants (0 - 27 days)
- Term newborn infants (0 - 27 days)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

- **Adult and elderly population (≥18 years)**

- Adults (18 to < 65 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)

- Elderly ( $\geq 65$  years)
    - Adults (65 to  $< 75$  years)
    - Adults (75 to  $< 85$  years)
    - Adults (85 years and over)
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### **Estimated number of subjects**

100

## Study design details

### **Data analysis plan**

Scientia Lab will analyse treatment journey of autoimmune patients using clinical and biological information. The results will be published in a peer-reviewed publications. Practice and patients' confidentiality will be maintained at any step of the study. Internal processes to ensure data safety and integrity are documented and have been shared with the data provider.

## 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)**

Optimum Patient Care Research Database

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**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