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

First published: 17/05/2024

Last updated: 17/05/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000159

Study ID

1000000159

DARWIN EU® study

No

Study countries

☐ France

Study status

Ongoing

Contact details

Study institution contact

Vincent Bouget vincent.bouget@scientalab.com

Study contact

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

Study start date

Actual: 27/04/2023

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

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

Anatomical Therapeutic Chemical (ATC) code

(L04AX03) methotrexate

methotrexate

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.

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 (≥ 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)

Estimated number of subjects

100

Study design details

Data analysis plan

Scienta Lab will 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

Data sources (types)

Electronic healthcare records (EHR)

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