# Psoriatic Arthritis Observational Study of Persistence of Treatment (PRO-SPIRIT Study)

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### Administrative details

#### **EU PAS number**

EUPAS31174

#### **Study ID**

31175

#### DARWIN EU® study

No

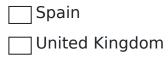
#### **Study countries**

Canada

France

Germany

ltaly



### **Study description**

The present observational study is to describe the 24-month persistence alongside effectiveness and healthcare resource use associated with bDMARD and tsDMARD treatments for PsA.

#### Study status

Planned

### Research institutions and networks

### Institutions

Syneos Health
United Kingdom
First published: 23/04/2015
Last updated: 06/03/2024
Institution Non-Pharmaceutical company ENCePP partner

### **Contact details**

### Study institution contact

Tamas Treuer treuert@lilly.com

Study contact

### Primary lead investigator

**Tamas Treuer** 

Primary lead investigator

## Study timelines

**Date when funding contract was signed** Planned: 01/06/2019

**Study start date** Planned: 31/10/2019

Date of final study report Planned: 31/10/2023

## Sources of funding

• Pharmaceutical company and other private sector

### More details on funding

Eli Lilly & Company

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

### Scope of the study:

Drug utilisation Effectiveness study (incl. comparative)

### Main study objective:

To describe persistence at 24 months among patients with PsA who initiate a new bDMARD or tsDMARD treatment including any tumor necrosis factor inhibitor (TNFi), ustekinumab, apremilast, ixekizumab, secukinumab, and tofacitinib, regardless of the line of therapy.

## Study Design

#### Non-interventional study design

Cohort

## Study drug and medical condition

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

IXEKIZUMAB SECUKINUMAB TOFACITINIB USTEKINUMAB APREMILAST

#### Anatomical Therapeutic Chemical (ATC) code

(L04AB) Tumor necrosis factor alpha (TNF-alpha) inhibitors Tumor necrosis factor alpha (TNF-alpha) inhibitors

#### Medical condition to be studied

Psoriatic arthropathy

### **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)

### Estimated number of subjects

1620

### Study design details

#### Outcomes

Persistence, PGA, HAQDI, PSAD

#### Data analysis plan

Persistence at Month 24 will be evaluated by Kaplan-Meier analysis of the time spent using the same bDMARD or tsDMARD initiated at baseline.

### Data management

### 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

### **Check completeness**

Unknown

### **Check stability**

Unknown

### Check logical consistency

Unknown

### Data characterisation

### Data characterisation conducted

No