

# Biological drugs in patients with psoriasis: a drug-utilization study using Tuscan administrative data banks

**First published:** 26/01/2022

**Last updated:** 31/03/2022

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS45365

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### Study ID

45366

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### DARWIN EU® study

No

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### Study countries

 Italy

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### Study description

This is a drug utilization study of biological drugs for psoriasis, in the Tuscany region of Italy, from 2011 to 2016.

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### Study status

Ongoing

## Research institutions and networks

### Institutions

#### University of Pisa

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Contact details

### Study institution contact

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Study contact

[ersilia.lucenteforte@unipi.it](mailto:ersilia.lucenteforte@unipi.it)

### Primary lead investigator

Ersilia Lucenteforte

Primary lead investigator

# Study timelines

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

Planned: 06/07/2020

Actual: 06/07/2020

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## **Study start date**

Planned: 01/05/2020

Actual: 01/05/2020

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## **Data analysis start date**

Planned: 01/06/2020

Actual: 01/06/2020

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## **Date of final study report**

Planned: 01/03/2022

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

University

# 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:**

Drug utilisation

**Main study objective:**

To evaluate the utilization of biologic drugs for psoriasis in the population of Tuscany using real-world data

### Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(L04AB04) adalimumab

adalimumab

(L04AB01) etanercept

etanercept

(L04AB02) infliximab

infliximab

(L04AC10) secukinumab

secukinumab

(L04AC05) ustekinumab

ustekinumab

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### **Medical condition to be studied**

Psoriasis

## Population studied

### **Age groups**

- Preterm newborn infants (0 - 27 days)
  - Term newborn infants (0 - 27 days)
  - Infants and toddlers (28 days - 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
  - 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**

2000

## Study design details

### **Outcomes**

- Identification of longitudinal patterns of adherence behavior through trajectory models - Investigation of switches of PSObio drugs

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### **Data analysis plan**

Treatment trajectories will be identified through two different methodological approaches: the first one is purely descriptive and it is based on the cluster analysis, whereas the second one is the group-based trajectory modeling (GBTM). Furthermore, patterns of switches will be identified using the state sequence analysis.

## 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)**

[Administrative healthcare records \(e.g., claims\)](#)

[Drug dispensing/prescription data](#)

[Other](#)

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### **Data sources (types), other**

Disease-specific exemptions from copayment

## 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