

# Drug utilization of biological drugs in patients over 65 years with Immune-mediated inflammatory diseases through the Italian VALORE network

**First published:** 04/10/2024

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Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000211

### Study ID

1000000211

### DARWIN EU® study

No

### Study countries

☐ Italy

### Study description

This study aims to assess the utilization of TNF-alpha inhibitors, anti-interleukin, selective immunosuppressants and anti-integrins in IMIDs patients over 65 years of age to shed a light of their use in clinical practice using data from the VALORE project, specifically observing persistence to biological therapies.

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## Study status

Planned

## Research institutions and networks

### Institutions

Pharmacology Unit - Veneto Pharmacovigilance Centre (Pharmacol UNIVR), University Hospital Verona

☐ Italy

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**Institution**

Educational Institution

Hospital/Clinic/Other health care facility

ENCePP partner

## Contact details

### Study institution contact

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**Study contact**

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**Primary lead investigator**

Andrea Spini

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 01/01/2020

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**Study start date**

Planned: 01/02/2024

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**Data analysis start date**

Planned: 01/04/2024

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**Date of final study report**

Planned: 31/12/0024

## Study protocol

[Protocol 65+ VALORE .pdf](#) (145.95 KB)

## Regulatory

**Was the study required by a regulatory body?**

Unknown

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

Non-EU RMP only

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Study design:**

retrospective, cohort study will be performed

**Main study objective:**

This study aims to assess the utilization of TNF-alpha inhibitors, anti-interleukin, selective immunosuppressants and anti-integrins in IMiDs patients over 65 years of age to shed a light of their use in clinical practice using data from the VALORE project, specifically observing persistence to biological therapies.

## Study Design

## Non-interventional study design

Cohort

## Study drug and medical condition

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

ABATACEPT

ADALIMUMAB

ANAKINRA

BRODALUMAB

CERTOLIZUMAB PEGOL

ETANERCEPT

GOLIMUMAB

GUSELKUMAB

INFLIXIMAB

IXEKIZUMAB

RISANKIZUMAB

SARILUMAB

SECUKINUMAB

TILDRAKIZUMAB

TOCILIZUMAB

USTEKINUMAB

VEDOLIZUMAB

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### Anatomical Therapeutic Chemical (ATC) code

(L04AA24) abatacept

abatacept

(L04AG05) vedolizumab

vedolizumab

(L04AB01) etanercept

etanercept

(L04AB02) infliximab

infliximab

(L04AB04) adalimumab

adalimumab

(L04AB05) certolizumab pegol

certolizumab pegol

(L04AB06) golimumab

golimumab

(L04AC03) anakinra

anakinra

(L04AC05) ustekinumab

ustekinumab

(L04AC07) tocilizumab

tocilizumab

(L04AC10) secukinumab

secukinumab

(L04AC12) brodalumab

brodalumab

(L04AC13) ixekizumab

ixekizumab

(L04AC14) sarilumab

sarilumab

(L04AC16) guselkumab

guselkumab

(L04AC17) tildrakizumab

tildrakizumab

(L04AC18) risankizumab

risankizumab

**Population studied**

## Short description of the study population

Elderly patients using biological drugs in the Italian Valore distributed database (2010-2022)

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### Age groups

- Elderly ( $\geq 65$  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 over 65 years

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### Estimated number of subjects

25000

## Study design details

### Setting

Italian setting

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### Comparators

None

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### Outcomes

Adherence, persistence of biological treatment

## Data management

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), other

Italian VALORE distributed database

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### Data sources (types)

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

## Use of a Common Data Model (CDM)

### CDM mapping

Yes

## Data quality specifications

### Check conformance

Yes

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### Check completeness

Yes

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### Check stability

Yes

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## **Check logical consistency**

Yes

## Data characterisation

### **Data characterisation conducted**

Unknown