# Post-marketing evaluation of the benefit-risk profile of originator biological drugs and biosimilars in the dermatological, rheumatological, gastroenterological and onco-hematological areas through the establishment of a single multiregional network for the integrated analysis of data from health databases, active surveillance and clinical registers - VALORE project

**First published:** 28/09/2021

**Last updated:** 13/03/2025

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS43274

**Study ID**

43960

**DARWIN EU® study**

No

**Study countries**

Italy

**Study description**

The nationwide multiregional Italian VALORE project set up a data infrastructure integrating claims data plus clinical registries from 16 Regions with the final aim of conducting post-marketing surveillance of biologics, including biosimilar, in patients with immune-mediated inflammatory diseases.

**Study status**

Ongoing

# Research institutions and networks

## Institutions

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

Italy

**First published:** 25/10/2022

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**Institution** | **Educational Institution** | **Hospital/Clinic/Other health care facility** | **ENCePP partner**

# Contact details

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# Study timelines

**Date when funding contract was signed**

Actual: 27/11/2020

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**Study start date**

Planned: 30/09/2021

Actual: 30/09/2021

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**Date of final study report**

Planned: 30/07/2023

# Sources of funding

- Other

# More details on funding

Italian Medicine Agency

# Regulatory

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

Yes

**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:**

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

**Main study objective:**

To establish a single multi-regional network aiming at set up a data infrastructure integrating claims data plus clinical registries from 16 Regions with the final aim of conducting post-marketing surveillance of biologics, including biosimilar, in patients with immune-mediated inflammatory diseases.

## Study Design

**Non-interventional study design**

Case-control

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

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

Tumor necrosis factor alpha (TNF-alpha) inhibitors

(L04AC) Interleukin inhibitors

Interleukin inhibitors

(L04AG05) vedolizumab

vedolizumab

(L04AA24) abatacept

abatacept

(L01FA01) rituximab

rituximab

(L01FD01) trastuzumab

trastuzumab

## 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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**Special population of interest**

Pregnant women

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**Estimated number of subjects**

160.000

## Study design details

**Data analysis plan**

Data will be described using frequencies, percentage, mean with standard deviations (or median with interquartile range, where appropriate). Prevalence of use (adjusted for age categories: < 18, 18–44, 45–64, ≥ 65 years) using a standardized direct method based on the calendar year-specific Italian population), proportion of biosimilar users, pattern of use of biological drugs (i.e. adherence, persistence, switch and swap) will be calculated. Subgroup analysis will be performed in children and adolescents (<18 years old), elderly patients (≥65 years old), pregnant women. Moreover, the main indication of use of biological drugs approved for immune-mediated inflammatory diseases will be identified using coding algorithms.

## Documents

**Study publications**

Trifirò G, Isgrò V, Ingrasciotta Y, Ientile V, L’Abbate L, Foti SS, Belleudi V,...

# 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)

Disease registry

## 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