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

Last updated: 13/03/2025

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

Gianluca Trifirò

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 27/11/2020

Study start date

Planned: 30/09/2021

Actual: 30/09/2021

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)

Special population of interest

Pregnant women

Estimated number of subjects

160000

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

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