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: 05/11/2021

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/43960

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 institution and networks

Institutions

Azienda Ospedaliera Universitaria Integrata Verona
First published: 01/02/2024
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01/02/2024

Institution
Educational Institution
Hospital/Clinic/Other health care facility

Contact details

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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
Cohort
Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(L04AB) Tumor necrosis factor alpha (TNF-alpha) inhibitors
(L04AC) Interleukin inhibitors
(L04AA33) vedolizumab
(L04AA24) abatacept
(L01XC02) rituximab
(L01XC03) 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

Data sources

Data sources (types)
Administrative data (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