Other data source

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Data source | Human

Administrative details

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000

Data source ID

1000

Data source acronym

Other DS

Data source qualification

If the data source has successfully undergone a formal qualification process (e.g., from the EMA, ISO or other certifications), this should be described.

No

Data source regions and languages

Data source establishment

Studies

List of studies that have been conducted using the data source

Spanish Real World Data on unresectable stage III NSCLC patients treated with durvalumab after chemoradiotherapy (S-REAL Study)

A Prospective, Non-interventional, Long-term, Multinational Cohort Safety Study of Patients with Hereditary Transthyretin Amyloidosis with Polyneuropathy (hATTR-PN) (TEG4001)

Prospective Cohort Study and Emulated Target Trial to Estimate the Safety and Effectiveness of MVA-BN vaccination against MPXV infection in at-risk individuals in Germany (SEMVAc/TEMVAc)

A Multicenter, Retrospective, Observational Study Using Real-world Data to Describe the Safety, Treatment Pattern and Effectiveness of Nirmatrelvir/Ritonavir among Patients treated with Nirmatrelvir/Ritonavir in China

A propensity score-matched analysis of depersonalized 4-week data from the German Pain e-Registry on the efficacy and tolerability of quinine sulphate vs. pridinol mesylate in the prevention and treatment of painful nocturnal leg cramps (PRISCILA)

TEST_ACR

Implementation of controlled access to and distribution of medicinal products in European Union (CONTROL-EU)

Long-Term, Observational, Global Registry of Patients With Generalized Myasthenia Gravis Who Have Received Treatment With Complement C5 Inhibition Therapies

Real-World Elranatamab Administration: Step Up Dosing (SUD), Treatment Patterns, and Healthcare Resource Utilization (HCRU) in Japan MDV Data

Real-world Comparative Effectiveness of Evolocumab Versus Ezetimibe in Reducing the Risk of Fatal and Nonfatal Myocardial Infarction (20240027)

Data elements collected

The data source contains the following information

Disease information

Does the data source collect information with a focus on a specific disease? This might be a patient registry or other similar initiatives.

No

Rare diseases

Are rare diseases captured? In the European Union a rare disease is one that affects no more than 5 people in 10,000.

No

Pregnancy and/or neonates

Does the data source collect information on pregnant women and/or neonatal subpopulation (under 28 days of age)?

No

Hospital admission and/or discharge

No

ICU admission

Is information on intensive care unit admission available?

No

Cause of death

Not Captured

Prescriptions of medicines

Not Captured

Dispensing of medicines

Not Captured

Advanced therapy medicinal products (ATMP)

Is information on advanced therapy medicinal products included? A medicinal product for human use that is either a gene therapy medicinal product, a somatic cell therapy product or a tissue engineered products as defined in Regulation (EC) No 1394/2007 [Reg (EC) No 1394/2007 Art 1(1)].

No

Contraception

Is information on the use of any type of contraception (oral, injectable, devices etc.) available?

No

Indication for use

Does the data source capture information on the therapeutic indication for the use of medicinal products?

Not Captured

Medical devices

Is information on medicinal devices (e.g., pens, syringes, inhalers) available?

No

Administration of vaccines

No

Procedures

Does the data source capture information on procedures (e.g., diagnostic tests, therapeutic, surgical interventions)?

Not Captured

Healthcare provider

Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available? The healthcare provider refers to individual health professionals or a health facility organisation licensed to provide health care diagnosis and treatment services including medication, surgery and medical devices.

No

Clinical measurements

Is information on clinical measurements (e.g., BMI, blood pressure, height) available?

No

Genetic data

Are data related to genotyping, genome sequencing available?

Not Captured

Biomarker data

Does the data source capture biomarker information? The term “biomarker” refers to a broad subcategory of medical signs (objective indications of medical state observed from outside the patient), which can be measured accurately and reproducibly. For example, haematological assays, infectious disease markers or metabolomic biomarkers.

Not Captured

Patient-reported outcomes

Is information on patient-reported outcomes (e.g., quality of life) available?

No

Patient-generated data

Is patient-generated information (e.g., from wearable devices) available?

No

Units of healthcare utilisation

Are units of healthcare utilisation (e.g., number of visits to GP per year, number of hospital days) available or can they be derived? Units of healthcare utilisation refer to the quantification of the use of services for the purpose of preventing or curing health problems.

No

Unique identifier for persons

Are patients uniquely identified in the data source?

No

Diagnostic codes

Not Captured

Medicinal product information

Not Captured

Quality of life measurements

Not Captured

Lifestyle factors

Not Captured

Sociodemographic information

Not Captured

Data flows and management

Access and validation

Biospecimen access

Are biospecimens available in the data source (e.g., tissue samples)?

No

Access to subject details

Can individual patients/practitioners/practices included in the data source be contacted?

No

Data source linkage

Linkage

Is the data source described created by the linkage of other data sources (prelinked data source) and/or can the data source be linked to other data source on an ad-hoc basis?

No

Data management specifications that apply for the data source

Possibility of data validation

Can validity of the data in the data source be verified (e.g., access to original medical charts)?

No

Data source preservation

Are records preserved in the data source indefinitely?

No

Approval for publication

Is an approval needed for publishing the results of a study using the data source?

No

Common Data Model (CDM) mapping

CDM mapping

Has the data source been converted (ETL-ed) to a common data model?

No