EULAR COVAX Registry

First published: 01/02/2024

Last updated: 17/10/2024

Data source Human Spontaneous reports of suspected adverse drug reactions

Vaccination registry

Administrative details

Administrative details

Data source ID

44876

Data holder

European Alliance of Associations for Rheumatology (EULAR)

Data source type

Spontaneous reports of suspected adverse drug reactions

Vaccination registry

Main financial support

Funding by own institution

Care setting

Other

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 website

https://www.eular.org/eular-covax-registry

Contact details

Diana Rodrigues diana.rodrigues@eular.org

Main

diana.rodrigues@eular.org

Data source regions and languages

Data source countries

Australia

Austria

Estonia

France

Germany

Greece

Hungary

Ireland

Italy

Latvia

Moldova, Republic of

Monaco

Russian Federation

Slovenia

Spain

Switzerland

Ukraine

United States

Data source languages

English

Data source establishment

Data source established

15/06/2021

Data source time span

First collection: 15/06/2020

The date when data started to be collected or extracted.

Last collection: 15/11/2022

If data collection in the data source has ceased, the date new records last

entered the data source.

Publications

Data source publications

Machado PM, Lawson-Tovey S, Strangfeld A, et alSafety of vaccination against SARS-CoV-2 in people with rheumatic and musculoskeletal diseases: results from the EULAR Coronavirus Vaccine (COVAX) physician-reported registryAnnals of the Rheumatic Diseases 2022;81:695-709.

Data elements collected

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.

Yes

Disease details (other)

Rheumatic and musculoskeletal diseases

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.

Yes

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?

Yes

Cause of death

Captured

Cause of death vocabulary

Other

Cause of death vocabulary, other

Own vocabulary for cause of death

Prescriptions of medicines

Captured

Prescriptions vocabulary

other

Prescriptions vocabulary, other

Own vocabulary for medication names

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

Yes

Procedures

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

Captured

Procedures vocabulary

Other

Procedures vocabulary, other

Own vocabulary for procedures

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?

Yes

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?

Yes

Diagnostic codes

Captured

Diagnosis / medical event vocabulary

Other

Diagnosis / medical event vocabulary, other

Own vocabulary for diagnosis/medical event

Medicinal product information

Not Captured

Quality of life measurements

Not Captured

Lifestyle factors

Not Captured

Sociodemographic information

Captured

Sociodemographic information collected

Age

Country of origin

Gender

Quantitative descriptors

Population Qualitative Data

Population age groups

Paediatric Population (< 18 years)

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)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated percentage of the population covered by the data source in the catchment area

Unsure

Description of the population covered by the data source in the catchment area whose data are not collected (e.g., people who are registered only for private care)

Regional sub-set - Cases of vaccination of patients with rheumatic and musculoskeletal diseases diagnoses by the date of the first dose of any vaccine against SARS-CoV-2, including cases since June 2020, from EULAR-affiliated countries together with the USA and Australia.

Population

Population size

10798

Active population size

10798

Population by age group

Age group	Population size	Active population size
Paediatric Population (< 18 years)	63	63
Preterm newborn infants (0 – 27 days)	0	0
Term newborn infants (0 – 27 days)	0	0
Infants and toddlers (28 days – 23 months)	2	2
Children (2 to < 12 years)	4	4
Adolescents (12 to < 18 years)	57	57
Adults (18 to < 46 years)	2167	2167
Adults (46 to < 65 years)	4418	4418
Elderly (≥ 65 years)	4150	4150
Adults (65 to < 75 years)	2329	2329
Adults (75 to < 85 years)	1517	1517
Adults (85 years and over)	304	304

Median observation time

Median time (years) between first and last available records for unique individuals captured in the data source

0.00

Median time (years) between first and last available records for unique active individuals (alive and currently registered) capt

0.00

Data flows and management

Access and validation

Governance details

Documents or webpages that describe the overall governance of the data source and processes and procedures for data capture and management, data quality check and validation results (governing data access or utilisation for research purposes).

https://www.eular.org/eular-covid-19-registry

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

Description of data collection

https://www.eular.org/eular-covax-registry

Event triggering registration

Event triggering registration of a person in the data source

Other

Event triggering registration of a person in the data source, other

COVID-19 vaccination

Event triggering creation of a record in the data source

Specialist encounter

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

Informed consent for use of data for research

Other

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

Data source preservation length (years)

10 years

Approval for publication

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

Yes

Informed consent, other

There is a committee to evaluate requests for data access.

Data source last refresh

15/11/2022

Common Data Model (CDM) mapping

CDM mapping

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

No