Rheumatoid Arthritis - Observation of Biologic Therapies

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Data source | Human | Disease registry

Administrative details

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PURI

https://redirect.ema.europa.eu/resource/45681

Data source ID

45681

Data source acronym

RABBIT

Data holder

German Rheumatism Research Centre Berlin (Deutsches Rheuma-Forschungszentrum Berlin, DRFZ)

Data source type

Disease registry

Main financial support

Funding from public-private partnership

Care setting

Hospital outpatient care

Primary care – specialist level (e.g. paediatricians)

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://biologika-register.de/

Contact details

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Data source regions and languages

Data source countries

Germany

Data source languages

German

Data source establishment

Data source established

01/04/2001

Data source time span

First collection: 01/04/2001

The date when data started to be collected or extracted.

Publications

Data source publications

Baganz L, Listing J, Kekow J, Eisterhues C, Wassenberg S, Zink A, Strangfeld A. Different risk profiles of biologic agents for new-onset psoriasis in patients with rheumatoid arthritis. InSeminars in Arthritis and Rheumatism 2020 Feb 1 (Vol. 50, No. 1, pp. 36-41). WB Saunders.

Schäfer M, Meißner Y, Kekow J, Berger S, Remstedt S, Manger B, Listing J, Strangfeld A, Zink A. Obesity reduces the real-world effectiveness of cytokine-targeted but not cell-targeted disease-modifying agents in rheumatoid arthritis. Rheumatology. 2020 Aug 1;59(8):1916-26.

Redeker I, Albrecht K, Kekow J, Burmester GR, Braun J, Schäfer M, Zink A, Strangfeld A. Risk of herpes zoster (shingles) in patients with rheumatoid arthritis under biologic, targeted synthetic and conventional synthetic DMARD

treatment: data from the German RABBIT register. Annals of the Rheumatic Diseases. 2022 Jan 1;81(1):41-7.

Schäfer M, Albrecht K, Kekow J, Rockwitz K, Liebhaber A, Zink A, Strangfeld A. Factors associated with treatment satisfaction in patients with rheumatoid arthritis: data from the biological register RABBIT. RMD open. 2020 Oct 1;6(3):e001290.

Meissner Y, Schaefer M, Schneider M, Wilden E, Zinke S, Zink A, Strangfeld A. Incidence of facial nerve palsies stratified by DMARD treatment in patients with rheumatoid arthritis: data from the RABBIT register. RMD open. 2020;6(3).

Studies

List of studies that have been conducted using the data source

Post-authorization Safety Surveillance Program for Sarilumab using existing European Rheumatoid Arthritis Registries in Germany, Spain, Sweden and United Kingdom

An Active Surveillance, Post Authorization Safety Study (PASS) to Estimate Incidence Rates of Serious Infection, Malignancy, Cardiovascular (CV) and Other Safety Events of Interest among all Patients Treated with Ruxience for Rheumatoid Arthritis (RA) within the German Registry Rheumatoide Arthritis: Beobachtung der Biologika Therapie (RABBIT)

Non-interventional post-authorization safety study of filgotinib in the treatment of patients with moderate to severe active rheumatoid arthritis within European registries

Non-interventional post-authorization cohort safety study evaluating the effectiveness of the additional risk minimization measures for filgotinib (Jyseleca®) use in patients with moderate to severe active rheumatoid arthritis within European registries

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

Rheumatoid arthritis

Disease details (other)

Disease information for rheumatoid arthritis: Disease activity measured by the DAS28 score (DAS28-ESR and DAS28-CRP) and CDAI (clinical disease activity index) and SDAI (simplified disease activity index). Functional status measured by the FFbH (Funktionsfragebogen Hannover) which can be transformed into HAQ values. Joint counts, joint surgeries, sleep disturbancies, level of fatigue, patient global).

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)?

Yes

Hospital admission and/or discharge

Yes

ICU admission

Is information on intensive care unit admission available?

Yes

Cause of death

Captured

Cause of death vocabulary

MedDRA

Prescriptions of medicines

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?

Captured

Indication vocabulary

MedDRA

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

ICD-10

MedDRA

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.

Yes

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.

Captured

Biomarker data vocabulary

Other

Biomarker vocabulary, other

lab values, free text.

Patient-reported outcomes

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

Yes

Patient-generated data

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

Yes

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

ICD-10

MedDRA

SNOMED

Medicinal product information

Captured

Medicinal product information collected

Brand name

Dosage regime

Dose

Route of administration

Medicinal product vocabulary

Not coded (Free text)

Quality of life measurements

Captured

Quality of life measurements vocabulary

SF-36

Lifestyle factors

Captured

Lifestyle factors

Alcohol use

Tobacco use

Sociodemographic information

Captured

Sociodemographic information collected

Age

Education level

Gender

Living in rural area

Other

Quantitative descriptors

Population Qualitative Data

Population age groups

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

Estimated prevalence of rheumatoid arthritis in Germany: 0,8 % = 560.000 patients /69,4 Millions inhibitants. Of those, ~ 25% receive advanced DMARD treatments (= 140.000 patients). RABBIT observes 22.000 patients. That is ~16% of the patient population of interest.

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)

Nation-wide collection of data from patients with rheumatoid arthritis from rheumatologists in private practice or outpatient clinics of hospitals.

Family linkage

Family linkage available in the data source permanently or can be created on an ad hoc basis

Ad hoc

Population

Population size

21979

Active population size

7655

Population by age group

Age group	Population size	Active population size
Adults (18 to < 46 years)	2472	796
Adults (46 to < 65 years)	9834	3483
Elderly (≥ 65 years)	9673	3376
Adults (65 to < 75 years)	5951	2170
Adults (75 to < 85 years)	3288	1032
Adults (85 years and over)	434	174

Median observation time

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

4.70

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

4.60

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://biologika-register.de/en/

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?

Yes

Description of data collection

Longitudinal observational cohort study; once enrolled, patients are observed for at least 5 and up to 10 years. Inclusion is with start of a biologic DMARD or a tsDMARD or a csDMARD after at least one csDMARD failure. Diagnose of rheumatoid arthritis has to be secured by the rheumatologists according to standard criteria.

Event triggering registration

Event triggering registration of a person in the data source

Start of treatment

Event triggering de-registration of a person in the data source

Death

Loss to follow up

Other

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

Patient declines further participation in the observation.

Event triggering creation of a record in the data source

After inclusion, new data is created on a regular base (without trigger). After 3 and 6 months and thereafter every 6 months, data is obtained from physicians and patients (e.g. regarding disease activity, treatment and treatment changes, reasons for that, adverse events, PROs). If no data is coming in at the intended time point of follow-up, reminders are sent to the physician.

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

Data source refresh

Every 6 months

Informed consent for use of data for research

Required for all studies

Possibility of data validation

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

Yes

Data source preservation

Are records preserved in the data source indefinitely?

Yes

Approval for publication

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

No

Data source last refresh

31/12/2022

Common Data Model (CDM) mapping

CDM mapping

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

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data source ETL CDM version

5.3.1

Data source ETL status

In progress

Data source ETL specifications (link)

https://ard.bmj.com/content/79/Suppl_1/177.2