British Society for Rheumatology Biologics Register for Rheumatoid Arthritis

First published: 01/02/2024

Last updated: 17/10/2024

Data source | Outdated | Human | Drug registry | Hospital discharge records | Other

Administrative details

Administrative details

Data source ID

23914

Data source acronym

BSRBR-RA

Data holder

University of Manchester

Data source type

Drug registry

Hospital discharge records

Other

Data source type, other

prospective studies database,case-control surveillance database

Main financial support

Funding from industry or contract research

Care setting

Secondary care – specialist level (ambulatory)

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.bsrbr.org/

Contact details

Kath Watson kath.watson@manchester.ac.uk

Main

kath.watson@manchester.ac.uk

Data source regions and languages

Data source countries

United Kingdom

Data source languages

English

Data source establishment

Data source established

15/06/2001

Data source time span

First collection: 01/10/2001

The date when data started to be collected or extracted.

Publications

Data source publications

Please see link for all of our publications.

Studies

List of studies that have been conducted using the data source

Post Marketing Safety Surveillance of Baricitinib in Three European Registries (I4V-MC-B012)

Survey on the collection of data on adverse events related to medicinal products through registries

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 British Society for Rheumatology Biologics

Register Rheumatoid Arthritis (BSRBR RA)

Long-term comparative safety cohort studies of upadacitinib (Rinvoq™) use for the treatment of RA in Europe

Drug utilisation study of upadacitinib (Rinvoq™) in Europe to evaluate the effectiveness of additional risk minimisation measures

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

An active surveillance, post-authorization safety study (PASS) of serious infection, malignancy, cardiovascular and other safety events of interest among patients treated with tofacitinib for moderately to severely active rheumatoid arthritis within the British Society for Rheumatology Biologics Register-Rheumatoid Arthritis (BSRBR-RA) (Safety of tofacitinib in BSRBR-RA)

Post-Authorisation Active Safety Surveillance Program Among Patients Treated With Tofacitinib for Polyarticular Juvenile Idiopathic Arthritis (pJIA) and Juvenile Psoriatic Arthritis (PsA) Within the United Kingdom (UK) Juvenile Idiopathic Arthritis (JIA) Biologics Register

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.

Yes

Disease details (other)

DAS28

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

Captured

Cause of death vocabulary

ICD-10

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?

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?

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?

Yes

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

Captured

Diagnosis / medical event vocabulary

MedDRA

Medicinal product information

Not Captured

Quality of life measurements

Not Captured

Lifestyle factors

Captured

Lifestyle factors

Tobacco use

Sociodemographic information

Captured

Sociodemographic information collected

Age

Deprivation index

Gender

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

Unknown - population covered is only those prescribed the drug and consented to participate in the study.

Population

Population size

30.000

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.bsrbr.org/hospitals/research-development/documents/

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.bsrbr.org/hospitals/data-collection/

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

Withdrawal

Event triggering creation of a record in the data source

Hospital

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

Common Data Model (CDM) mapping

CDM mapping

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

No