

Biologika in der Kinderrheumatologie

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Data source

Human

Disease registry

Other

Administrative details

Administrative details

Data source ID

47820

Data source acronym

BIKER

Data holder

Biologika in der Kinderrheumatologie-Register (BIKER) at the Asklepios Klinik
Sankt Augustin

Data source type

Disease registry

Other

Data source type, other

Exposure registry, prospective studies 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.biker-register.de>

Contact details

Gerd Horneff g.horneff@asklepios.com

Main

g.horneff@asklepios.com

Angela Zimmer a.zimmer@asklepios.com

Alternate

a.zimmer@asklepios.com

Data source regions and languages

Data source countries

Austria

Germany

Data source languages

German

Data source establishment

Data source established

01/01/2001

Data source time span

First collection: 01/01/2001

The date when data started to be collected or extracted.

Publications

Data source publications

[Thiele F, Klein A, Hospach A, Windschall D, Mrusek S, Ruehlmann JM, Horneff G. Efficacy and Safety of Etanercept Biosimilars Compared With the Originator for Treatment of Juvenile Arthritis: A Prospective Observational Study. ACR Open Rheumatol. 2021 Nov;3\(11\):779-787.](#)

[Thiele F, Klein A, Klotsche J, Windschall D, Dressler F, Kuemmerle-Deschner J, Minden K, Foeldvari I, Foell D, Mrusek S, Oommen PT, Horneff G. Biologics with or without methotrexate in treatment of polyarticular juvenile idiopathic arthritis: effectiveness, safety and drug survival. Rheumatology \(Oxford\). 2022 Oct 12;keac587.](#)

Broekaert IJ, Klein A, Windschall D, Rogalski B, Weller-Heinemann F, Oommen P, Küster M, Foeldvari I, Minden K, Hospach A, Hufnagel M, Berger T, Geikowski T, Quietzs J, Horneff G. Development of Inflammatory Bowel Disease in Children With Juvenile Idiopathic Arthritis Treated With Biologics. *J Pediatr Gastroenterol Nutr.* 2023 Feb 1;76(2):174-182.

Comparison of treatment response, remission rate and drug adherence in polyarticular juvenile idiopathic arthritis patients treated with etanercept, adalimumab or tocilizumab. Horneff G, Klein A, Klotsche J, Minden K, Huppertz H, Weller-Heinemann F, Kuemmerle-Deschner J, Haas JP, Hospach A. *Arthritis Res Ther.* 2016 Nov 24;18(1):272.

Safety of biologic therapies for the treatment of juvenile idiopathic arthritis. Horneff G. *Expert Opin Drug Saf.* 2015 Jul;14(7):1111-26. doi: 10.1517/14740338.2015.1042453. Review

Studies

List of studies that have been conducted using the data source

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

An observational post-approval safety study of golimumab in treatment of polyarticular Juvenile Idiopathic Arthritis (pJIA) using the German Biologics JIA Registry (BiKeR) (MK-8259-050)

Post-Authorisation Active Safety Surveillance Program Among Patients Treated With Tofacitinib for Polyarticular Juvenile Idiopathic Arthritis (pJIA) and Juvenile Psoriatic Arthritis (PsA) Within the German Biologics in Pediatric Rheumatology Registry (BiKeR) and Juvenile Arthritis Methotrexate/Biologics Long-term Observation (JuMBO) Registries (BiKeRJuMBO)

Data elements collected

The data source contains the following

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)

Single and compound disease activity measures on juvenile idiopathic arthritis:
Kind and number of swollen/tender/active joints, Joints with limitation of motion,
Levels of ESR, CRP, Childhood-Health-Assessment Questionnaire, Global disease
activity by parent/patient and physician , Presence or absence of fever, Rash,
Pericarditis, Pleuritis

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

ICD-10

Other

Cause of death vocabulary, other

SAE

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?

Yes

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

CPT

HCPCS

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.

Captured

Biomarker data vocabulary

Other

Biomarker vocabulary, other

HLA-B27, Antinuclear antibody positivity, CCP-antibody positivity, CRP, ESR

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

Medicinal product information

Captured

Medicinal product information collected

Brand name

Dose

Medicinal product vocabulary

Other

If 'other,' what vocabulary is used?

ATC Classification

Quality of life measurements

Not Captured

Lifestyle factors

Captured

Lifestyle factors

Alcohol use

Sociodemographic information

Captured

Sociodemographic information collected

Age

Gender

Country of origin

Ethnicity

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)

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

50%

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

Population

Population size

5172

Active population size

833

Population by age group

Age group	Population size	Active population size
Paediatric Population (< 18 years)	5088	790
Infants and toddlers (28 days - 23 months)	126	2
Children (2 to < 12 years)	2157	259
Adolescents (12 to < 18 years)	2517	423
Adults (18 to < 46 years)	84	43

Median observation time

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

2.07

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

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).

<http://biker-register.de/index.php?page=formulare-downloads>

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

Paper CRF

Event triggering registration

Event triggering registration of a person in the data source

Start of treatment

Other

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

Adverse events

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

Loss to follow up

Other

Event triggering de-registration of a person in the data source, other
age > 18 years

Event triggering creation of a record in the data source
Adverse event or major change of treatment

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

Other

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?

Yes

Informed consent, other

There is a committee to evaluate requests for data access

Data source last refresh

24/04/2023

Common Data Model (CDM) mapping

CDM mapping

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

No