MS-Register of the National MS-Society of Germany (DMSG, Bundesverband e.V.)

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Data source **Human** **Disease registry** **Primary care medical records**

Spontaneous reports of suspected adverse drug reactions

Administrative details

Administrative details

Data source ID

47729

Data source acronym

German MS-Register

Data holder

MS Forschungs- und Projektentwicklungs-gGmbH (MSFP-gGmbH)

Data source type

Disease registry

Primary care medical records

Spontaneous reports of suspected adverse drug reactions

Main financial support

Funding from industry or contract research

Funds from patients organisations, charity and foundations

Care setting

Hospital inpatient care

Hospital outpatient care

Other

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

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.msregister.de

Contact details

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Main

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Data source regions and languages

Data source countries

Germany

Data source languages

German

Data source establishment

Data source established

15/06/2001

Data source time span

First collection: 15/06/2001

The date when data started to be collected or extracted.

Publications

Data source publications

Therapy switches in fingolimod-treated patients with multiple sclerosis: long-term experience from the German MS Registry. Frahm N, Fneish F, Ellenberger D, et al., 2022: Neurology and Therapy article published online: 12 January 2022, doi:10.1007/s40120-021-00320-w

Aggressive multiple sclerosis – a matter of measurement and timing. Ellenberger D, Flachenecker P, Fneish F, Frahm N,Hellwig K, Paul F, Stahmann A, Warnke C, Rommer PS, Zettl UK, 2020: BRAIN published online: September 2020, doi:10.1093/brain/awaa306

Prevalence of pediatric multiple sclerosis in Germany - a nationwide population -based analysis of outpatient insurance claims. Frahm N, Peters M, Bätzing J, Ellenberger D, Akmatov MK, Haas J, Rommer PS, Stahmann A, Zettl UK, Holstiege J, 2021: European Journal of Neurology Vol 28, Issue 9, p3173-3176, first published online: July 9, 2021, doi:10.1111/ene.15015

Treatment patterns in pediatric patients with multiple sclerosis in Germany - a nationwide claims-based analysis. Frahm N, Peters M, Bätzing J, Ellenberger D, Akmatov MK, Haas J, Rommer PS, Stahmann A, Zettl UK, Holstiege J, 2021: Therapeutic Advances in Neurological Disorders published online: October 6, 2021, doi:10.1177/17562864211048336

Associations of Disease-Modifying Therapies With COVID-19 Severity in Multiple Sclerosis. Simpson-Yap S, Stahmann A, et al., 2021: Neurology Article first published online: October 5, 2021, doi:10.1212/WNL.0000000000012753

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

Ozanimod Real-World Safety - A Post-Authorisation Multi-National Long-term Non-Interventional Study (ORION)

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

Multiple sclerosis

Disease details (other)

G35.x Multiple Sclerosis

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)?

Yes

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

ICD-10

Prescriptions of medicines

Captured

Prescriptions vocabulary

other

Prescriptions vocabulary, other

ATC, German PZN

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

ICD-10

Medical devices

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

Yes

Administration of vaccines

Yes

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?

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

MedDRA

Medicinal product information

Captured

Medicinal product information collected

Batch number

Brand name

Dosage regime

Medicinal product vocabulary

Other

If 'other,' what vocabulary is used?

In-house developed list that contains all for MS approved drugs

Quality of life measurements

Captured

Quality of life measurements vocabulary

other

Quality of life measurements, other

MSIS-29v1

Lifestyle factors

Not Captured

Sociodemographic information

Captured

Sociodemographic information collected

Age

Education level

Gender

Marital status

Socioeconomic status

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

33%

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

81252

Active population size

41401

Population by age group

Age group	Population size	Active population size

Adults (18 to < 46 years)	36990	17975
Adults (46 to < 65 years)	38289	20331
Elderly (≥ 65 years)	5973	3095
Adults (65 to < 75 years)	4902	2514
Adults (75 to < 85 years)	1028	563
Adults (85 years and over)	43	18

Median observation time

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

3.00

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

3.70

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.msregister.de/forschung/nutzung-von-registerdaten-use-and-access/

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

In the majority of our centers, staff logins into our research database using individual accounts and then enters data on their centers pwMS population using the pseudonym generated by the central trusted 3rd party. Data collection by patients can be enabled by the centers using either individual accounts details or visit specific tokens provided to the patients as qr-codes or email links.

Event triggering registration

Event triggering registration of a person in the data source

Disease diagnosis

Practice registration

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

Death

Emigration

Other

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

Patient revokes ICF

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?

Yes

Linkage description, possible linkage

Health insurance data: Via a trusted 3rd party we can link between the registry and other data sources by employing probabilistic matching on the identifying data (e.g. names, date of birth, sex and diagnosis code). IRB confirmation is needed.

Regims-registry: linkage is possible through deterministic matching using patient common ID.

Linked data sources

Pre linked

Is the data source described created by the linkage of other data sources?

No

Data source, other

Health insurance data

Linkage strategy

Probabilistic

Linkage variable

Not applicable (multiple variables used in probabilistic linkage strategy)

Linkage completeness

Completness will depend on the number of insurers included in the linkage.

Pre linked

Is the data source described created by the linkage of other data sources?

No

Data source, other

Regims-registry

Linkage strategy

Deterministic

Linkage variable

Common ID

Linkage completeness

Completness will depend on the number of insurers included in the linkage.

Data management specifications that apply for the data source

Data source refresh

Monthly

Informed consent for use of data for research

Required for general use

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

Data source last refresh

01/06/2023

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

Completed