Registro Italiano Sclerosi Multipla e Patologie Correlate (Italian Multiple Sclerosis and Related Disorders Register)

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Data source | Human | Disease registry

Administrative details

Administrative details

Data source ID

1000000797

Data source acronym

RISM

Data holder

The Italian Multiple Sclerosis and Related Disorders Register (RISM) – Research Unit “Italian Multiple Sclerosis Foundation and University of Bari”

Data source type

Disease registry

Main financial support

Funds from patients organisations, charity and foundations

Care setting

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

Registro Italiano Sclerosi Multipla e Patologie Correlate

Contact details

Mario Alberto Battaglia presidenza@aism.it

Main

presidenza@aism.it

Michela Ponzio michela.ponzio@aism.it

Alternate

michela.ponzio@aism.it

Data source regions and languages

Data source countries

Italy

Data source languages

Italian

Data source establishment

Data source established

17/09/2014

Data source time span

First collection: 17/09/2014

The date when data started to be collected or extracted.

Publications

Data source publications

Trojano M, Bergamaschi R, Amato MP, et al. The Italian multiple sclerosis register. Neurological Sciences. 2019;40(1):155-165.

Mosconi P, Guerra T, Paletta P, et al. Data monitoring roadmap: The experience of the Italian Multiple Sclerosis and Related Disorders Register. Neurological Sciences. 2023;44(12):4001-4011.

Ponzio M, Battaglia MA, Trojano M, et al. I registri come importante fonte di real world data: l'esperienza del Registro Italiano Sclerosi Multipla e Patologie Correlate [Registers as central real world data source: the experience of the Italian Multiple Sclerosis and Related Disorders Register]. Epidemiol Prev. 2024;48(4-5):361-374.

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

Neuromyelitis optica spectrum disorder

Myelin oligodendrocyte glycoprotein antibody-associated disease

Disease details (other)

undefined

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

Yes

ICU admission

Is information on intensive care unit admission available?

No

Cause of death

Captured

Cause of death vocabulary

MedDRA

Prescriptions of medicines

Captured

Prescriptions vocabulary

ATC

Dispensing of medicines

Captured

Dispensing vocabulary

ATC

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?

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

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.

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

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?

Yes

Diagnostic codes

Captured

Diagnosis / medical event vocabulary

ICD-9-CM

MedDRA

Other

Diagnosis / medical event vocabulary, other

Dropdown menu with a predefined list of MS and related disorder diagnoses (NMOSD, MOGAD).

Medicinal product information

Captured

Medicinal product information collected

Active ingredient(s)

Brand name

Dosage regime

Dose

Route of administration

Medicinal product vocabulary

ATC

Quality of life measurements

Captured

Quality of life measurements vocabulary

QOLS

Lifestyle factors

Captured

Lifestyle factors

Other

Tobacco use

Lifestyle factors included other

Only for patients under 18 years: sunlight exposure, tobacco exposure

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Sociodemographic information

Captured

Sociodemographic information collected

Age

Country of origin

Education level

Ethnicity

Other

Sex

Sociodemographic information other

Occupational status

Quantitative descriptors

Population Qualitative Data

Population age groups

Paediatric Population (< 18 years)

Neonate

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adult and elderly population (≥18 years)

Adults (18 to < 65 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

Approximately 70% of the Italian multiple sclerosis population and 40% of the NMOSD population are covered by RISM in Italy (prevalence estimates according to the document “Barometro della Sclerosi Multipla e Patologie Correlate 2025”, published by the Italian Multiple Sclerosis Patient Society – Associazione Italiana Sclerosi Multipla, AISM).

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)

Data from patients with multiple sclerosis or related disorders (NMOSD and MOGAD) are not collected if:

- patients do not provide informed consent;
- patients are not followed by a specialised multiple sclerosis clinical centre; or
- the specialised clinical centre does not participate in the RISM network of centres.

Population

Population size

96034

Population by age group

Age group	Population size
Paediatric Population (< 18 years)	173
Adults (18 to < 65 years)	77829
Elderly (≥ 65 years)	18032

Median observation time

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

7.46

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).

The Italian Multiple Sclerosis and Related Disorders Register. Manual of Procedures, v5.0, 20 June 2025

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

In 2000, the Italian collection of MS clinical data started at different Italian MS centres in the framework of the Italian Multiple Sclerosis Database Network (MSDN). At the end of 2014, the Italian Multiple Sclerosis and Related Disorders Register (RISM) was set up to create a national data source collecting demographic and clinical data on people with multiple sclerosis.
Currently, data are collected through a web-based system - the RISM-App - developed ad hoc for the study. Each centre can enter the data after identification through a personalised password. In RISM, each patient is assigned to a specific centre and has a unique valid code identifier, obtained through the patient encrypted fiscal code.
The RISM-App includes 1,475 variables and is organised into sections and sub-sections. According to the current clinical practice, the following information is requested in the RISM-App: Identification/Personal data; Onset and Diagnosis (Anamnesis); Follow-up visits – EDSS, Safety; Relapses; Adverse events (clinical events); Treatments; Non-pharmacological treatments; Risk assessment; Pregnancies; COVID-19; Co-morbidity; Familiar anamnesis; Tests and scales; Laboratory exams; Magnetic Resonance, Liquor, Evoked Potentials; EEG, ECG, Blood pressure; Eye examination; Optical Computerised Tomography.

To harmonise data collection, the RISM-App integrates several standardised databases, including FarmaDati, MedDRA, ICD-9-CM, and EUROCAT (for congenital anomalies). Continuous data monitoring is ensured through regular communication with centres, biannual ad hoc reports providing both overall and centre-specific quality and descriptive indicators, data verification requests, and training on standardised data collection procedures. In addition, a set of built-in validation checks — such as consistency between date of birth, diagnosis, first visit, and treatment — is implemented in the RISM-App to prevent data inconsistencies.

Event triggering registration

Event triggering registration of a person in the data source

Disease diagnosis

Practice registration

Start of treatment

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

Death

Emigration

Loss to follow up

Event triggering creation of a record in the data source

Clinical centers invite patients to be enrolled in RISM. After signing the informed consent of the study, a record is created to collect patients' demographic and clinical information.

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

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?

No

Data source preservation length (years)

20 years

Approval for publication

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

Yes

Common Data Model (CDM) mapping

CDM mapping

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

No