Czech Registry of Monoclonal Gammopathies

First published: 31/10/2022

Last updated: 17/10/2024

Data source | Human | Cancer registry | Disease registry | Hospital inpatient records | Hospital outpatient visit records | Other

Administrative details

Administrative details

Data source ID

1111180

Data source acronym

RMG

Data holder

Institute of Biostatistics and Analyses (IBA)

Data source type

Cancer registry

Disease registry

Hospital inpatient records

Hospital outpatient visit records

Other

Data source type, other

Registry of Monoclonal Gammopathies

Main financial support

European public funding

Funding by own institution

Funding from industry or contract research

Care setting

Hospital inpatient care

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://rmg.healthregistry.org/index.php

Contact details

Roman Hájek roman.hajek@fno.cz

Main

roman.hajek@fno.cz

Lenka Mokrá helpdesk@biostatistika.cz

Alternate

helpdesk@biostatistika.cz

Data source regions and languages

Data source countries

Czechia

Data source languages

English

Data source establishment

Data source established

01/05/2007

Data source time span

First collection: 01/05/2007

The date when data started to be collected or extracted.

Publications

Data source publications

Registry of Monoclonal Gammopathies - Publications

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

Monoclonal gammopathy

Disease details (other)

MGUS - D47.2SMM -D90.0MM - D90.0 WM - C88.0AL AMYL - E85

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)?

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

Not coded (Free text)

Prescriptions of medicines

Captured

Dispensing of medicines

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)].

Yes

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

Other

Indication vocabulary, other

ICD-O3

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

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?

Captured

Genetic data vocabulary

Other

Genetic data vocabulary, other

Genetic abberation

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?

No

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-10

MedDRA

Other

Diagnosis / medical event vocabulary, other

ICD-03

Medicinal product information

Captured

Medicinal product information collected

Dosage regime

Dose

Route of administration

Medicinal product vocabulary

Not coded (Free text)

Quality of life measurements

Not Captured

Lifestyle factors

Not Captured

Sociodemographic information

Captured

Sociodemographic information collected

Age

Country of origin

Sex

Quantitative descriptors

Population Qualitative Data

Population age groups

Adults (18 to < 46 years)

Adults (46 to < 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

~80% of MG cases in Czechia Population size:

14245 in total, one patient can have more than one diagnosis:

MM - 8 973

MGUS - 5 232

SMM - 348

WM - 306

AL AMYL - 88

Median observation time:

MGUS - 6.0 years

SMM - 4.6 years

MM - 2.9 years

WM - 4.7 years

AL AMYL - 1.1 years

Population size active:

MM - 3 620

MGUS - 3 482

SMM - 219

WM - 149

AL AMYL - 32

Median observation time active:

MGUS - 6.0 years

SMM - 4.6 years

MM - 3.5 years

WM - 5.0 years

AL AMYL - 2.0 years

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)

Czech RMG only captures patients that have provided informed consent and are treated in any of the centres that participate in the registry on a voluntary basis. Any patient that has not provided informed consent or is treated at any non-participating centre will therefore not be captured in the data source

Population

Population size

15245

Population by age group

Age group	Population size
Adults (18 to < 46 years)	326
Adults (46 to < 65 years)	3477
Adults (65 to < 75 years)	5129
Adults (75 to < 85 years)	4119
Adults (85 years and over)	994

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://rmg.healthregistry.org/index.php

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

The data are collected via electronic data capture system called CLADE-IS (https://www.clade-is.com/).

Event triggering registration

Event triggering registration of a person in the data source

Disease diagnosis

Other

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

Patient's signature of Informed consent

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 withdrawl of informed consent

Event triggering creation of a record in the data source

Data is collected for each visit, including patient status and are updated twice yearly per patient by data manager at participating sites.

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

Monthly

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?

Yes

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_adj

Data source ETL status

Completed