Therapy Monitor Multiple Myeloma Germany

First published: 01/02/2024

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Data source | Human | Other

Administrative details

Administrative details

Data source ID

1111168

Data source acronym

TM MM DE

Data holder

TriNetX Oncology GmbH

Data source type

Other

Data source type, other

Curated Chart Review Database

Main financial support

Funding from industry or contract research

Care setting

Other

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://trinetx.com/products/consulting-services/tnxogmbh/

Contact details

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Data source regions and languages

Data source countries

Germany

Data source languages

German

English

Data source establishment

Data source established

01/01/2016

Data source time span

First collection: 01/01/2016

The date when data started to be collected or extracted.

Publications

Data source publications

Evolving Treatment Trends in Relapsed/Refractory Multiple Myeloma in Europe from 2016 to 2018:Analysis of a Multi-National Survey

Treatment Patterns in Patients with Refractory/Relapsed Multiple Myeloma in Germany Between 2016 and 2018

Baseline characteristics and survival outcomes of patients with tri-exposed multiple myeloma in a German registry

Adjusted comparison of outcomes between patients from CARTITUDE-1 versus multiple myeloma patients with prior exposure to PI, IMiD and anti-CD-38 from a German registry

Diagnosis and treatment of multiple myeloma in Germany – Analysis of a nationwide, multi-institutional survey

Studies

List of studies that have been conducted using the data source

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)

Multiple myeloma, including all diagnostic and clinical variables acording to current guidelines for each time point of treatment decision after disease progression, retrospectively to the initial diagnosis. Disease and treatment characteristics include relevant biomarkers, labs, limited information on care-relevant comorbidities, detailed descriptions on disease-specific interventions and/or therapy measures (systemic therapy, stem cell transplant and CAR-T cell therapy), details of progression controls performed, best response, treatment pauses/interruption/modification and reason change in treatment plan.

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

Not Captured

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?

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?

No

Administration of vaccines

No

Procedures

Does the data source capture information on procedures (e.g., diagnostic tests, therapeutic, surgical interventions)?

Captured

Procedures vocabulary

Not coded (Free text)

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.

Yes

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

Standard vocabulary not used

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

Standard vocabulary not used

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.

Yes

Unique identifier for persons

Are patients uniquely identified in the data source?

Yes

Diagnostic codes

Captured

Diagnosis / medical event vocabulary

Not coded (Free text)

Medicinal product information

Captured

Medicinal product information collected

Active ingredient(s)

Dose

Dosage regime

Route of administration

Brand name

Medicinal product vocabulary

Not coded (Free text)

Quality of life measurements

Not Captured

Lifestyle factors

Captured

Lifestyle factors

Other

Sociodemographic information

Captured

Sociodemographic information collected

Age

Gender

Education level

Health area

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

12-13% of the treated prevalence in Germany based on internal MM prevalence projections from 2018 coherent with secondary official sources (RKI) and accepted by the G-BA and for AMNOG submissions.

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)

Captured population has complete data reporting.

Population

Population size

8412

Active population size

3762

Population by age group

Age group	Population size	Active population size
Adults (18 to < 46 years)	73	41
Adults (46 to < 65 years)	1569	815
Elderly (≥ 65 years)	6770	2906

Age group	Population size	Active population size
Adults (65 to < 75 years)	3722	1488
Adults (75 to < 85 years)	2689	1255
Adults (85 years and over)	359	163

Median observation time

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

6.50

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

3.00

Data flows and management

Access and validation

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

Participating centers enter data from patient records to an online eCRF created by TriNetX Oncology GmbH in the current version of secuTrial™ (iAS GmbH, Berlin, Germany). Participant selection is driven by the distribution of the number of MM patients in the relevant health care sectors (university hospitals, non-university hospitals, office-based practice) obtained from in-house health care structure analyses. The documenting physician transfers the existing data from the patient file to the online documentation form retrospectively from the current point in time (end of the observation period) to the initial diagnosis of the disease.

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

Patient's who have been de-registered remain in the database for retrospectice and longitudinal analyses.

Event triggering creation of a record in the data source

New patient meeting the inclusion criteria is reported via eCRF by the participating physician

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

Quarterly

Informed consent for use of data for research

Not Required

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?

No

Data source last refresh

31/12/2022

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

5.4

Data source ETL frequency

6,00 months

Data source ETL status

Completed