

# A global, prospective, non-interventional, observational study of presentation, treatment patterns, and outcomes in multiple myeloma patients - the INSIGHT-MM study

**First published:** 06/08/2021

**Last updated:** 25/06/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS41735

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### Study ID

48872

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### DARWIN EU® study














No

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### Study countries

 Belgium

 Brazil

-  China
  -  Colombia
  -  France
  -  Germany
  -  Greece
  -  Israel
  -  Italy
  -  Mexico
  -  Spain
  -  Taiwan
  -  Türkiye
  -  United Kingdom
  -  United States
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### **Study description**

The purpose of this study is to describe contemporary, real-world patterns of patient characteristics, clinical disease presentation, therapeutic regimen chosen, and clinical outcomes in participants with newly diagnosed ND multiple myeloma (MM) and participants with relapsed/refractory R/R MM.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

Takeda

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

Multiple centres: 134 centres are involved in the study

## Contact details

### Study institution contact

Study Contact Takeda [TrialDisclosures@takeda.com](mailto:TrialDisclosures@takeda.com)

**Study contact**

[TrialDisclosures@takeda.com](mailto:TrialDisclosures@takeda.com)

### Primary lead investigator

Study Contact Takeda

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Actual: 30/06/2016

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### Study start date

Actual: 01/07/2016

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### **Data analysis start date**

Actual: 03/07/2021

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### **Date of final study report**

Planned: 11/08/2022

Actual: 08/08/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Takeda

## Study protocol

[NSMM-5001 INSIGHT MM Protocol-Redacted.pdf](#) (1.59 MB)

[NSMM-5001 INSIGHT MM Protocol Amend 2-Redacted.pdf](#) (1.59 MB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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### **Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 2 (specific obligation of marketing authorisation)

## Methodological aspects

### Study type

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

The primary objective of this study is to describe contemporary, real-world disease and patient presentation, therapies, and clinical outcomes in participants with ND MM and participants with R/R MM.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

Plasma cell myeloma

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**Additional medical condition(s)**

Newly diagnosed multiple myeloma within 3 months from initiation of treatment. Relapsed/refractory multiple myeloma who have received 1-3 prior lines of treatment.

## Population studied

### **Short description of the study population**

The study included both newly diagnosed and relapsed/refractory multiple myeloma patients aged 18 years or older between July 2016 and November 2018 at 136 centers in 15 countries.

Inclusion Criteria:

- Is 18 years of age or older.
- Is experiencing one of the following:
  - a) Newly diagnosed multiple myeloma (MM) within 3 months from initiation of treatment with documented month and year of diagnosis, criteria met for diagnosis, stage, and MM-directed treatment history, including duration.
  - b) Relapsed/refractory MM who have received 1 to 3 prior lines of therapy with documented data in the medical record regarding diagnosis (month and year), the regimens used in 1st, 2nd, and 3rd line as applicable, whether stem cell transplant was part of 1st, 2nd, and 3rd line of therapy, whether consolidation/maintenance was part of 1st, 2nd, and 3rd line of therapy, also whether investigational therapy/treated on a clinical trial was part of any of these regimens.
- Patients willing and able to complete PROs in accordance with local regulatory and data protection requirements will be enrolled.
- Is willing and able to sign informed consent to participate.

Exclusion Criteria:

- Patients reporting to a site in this study for a second opinion (consultation

only) or patients whose frequency of consult and follow-up are not adequate for quarterly electronic case report form (eCRF) completion.

- Participation in another study (observational or interventional) that prohibits participation in this study.
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### **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)
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### **Special population of interest**

Other

Renal impaired

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### **Special population of interest, other**

Relapsed/refractory multiple myeloma patients

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### **Estimated number of subjects**

4200

## **Study design details**

### **Outcomes**

The primary outcomes will assess the number of participants with co-morbidities, diagnosed and with symptoms of ND MM and R/R MM, sites of disease, ECOG performance status, frailty index, participants evaluated for laboratory test, duration for treatment, overall survival, progression status,

response to each regimen, time to next therapy and participants with stem cell transplant. Secondary outcomes are treatment combinations,sequencing,rechallenge,clinical outcomes for different strategies,between continuous and intermittent,triggers of treatment initiation at relapse,biochemical progression/symptomatic progression,reasons for treatment modifications,HRQoL,HRU,associations between presentation,disease characteristics,choice of therapy and clinical outcomes,SAE and non-SAE.

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### **Data analysis plan**

Population characteristics (including demographics, medical conditions, duration of disease, and types of therapy used at study entry) and all relevant primary and secondary outcomes measures will be summarized as mean, standard deviation, minimum, maximum, median, 25th and 75th percentile, and 95% confidence interval (CI) of the mean for continuous variables, and count and proportion with 95% CI of the proportion for categorical data as appropriate. Descriptive statistics will be used to describe treatment patterns, safety assessments, clinical outcomes, economic outcomes, and HRQoL self-reported outcomes observed during the study period. Outcomes of interest (DOT, PFS, TTNT, OS) will be analyzed using Kaplan Meier methods/estimates and will be adjusted using Cox PH regression models to account for covariates that could impact treatment regimen assignment and outcomes.

## Documents

### **Study results**

[NSMM-5001\\_RDS CSR Synopsis \(including 2 Addendums\)\\_2022-Sep-28.pdf](#)  
(1008.53 KB)

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## Data management

## ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data sources (types)

[Other](#)

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### Data sources (types), other

Prospective patient-based data collection, Data collection will be done prospectively as per the standard schedule of routine office visits for MM participants.

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No