

# Description of the management and outcomes of patients with frontline transplant-eligible multiple myeloma in four European countries (France, Germany, Spain and Italy)

<b>Submission date</b> 15/11/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/11/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 22/11/2021	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study aims to provide insights on the current standard of care for the management of patients with frontline transplant eligible (FLTE) multiple myeloma (MM) in four European countries (France, Germany, Italy, and Spain). It aims also to investigate changes in the use of the different treatments in these patients in recent years (2017 – 2019). Finally, the outcomes associated with each treatment will be described.

### Who can participate?

Data from patients with multiple myeloma based on their medical records.

### What does the study involve?

Data on the patients will be extracted from databases in France, Germany, Italy, and Spain.

### What are the possible benefits and risks of participating?

There are no expected benefits or risks to the participants.

### Where is the study run from?

Kantar Health (France)

### When is the study starting and how long is it expected to run for?

June 2021 to August 2021

### Who is funding the study:

Janssen EMEA (Belgium)

### Who is the main contact?

Sophie Marguet

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# Contact information

## Type(s)

Scientific

## Contact name

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# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

PCSONC003873

# Study information

## Scientific Title

Real-world study of the management and outcomes of patients with frontline transplant-eligible multiple myeloma in four European countries (France, Germany, Spain and Italy)

## Study objectives

Which treatment regimen is considered the current standard of care in the selected European countries (France, Germany, Spain, Italy) for the management of patients with frontline transplant eligible multiple myeloma (FLTE MM) and what has been the evolution of the use of the different regimens in recent years?

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

This study does not require ethics approval. As this is an observational study that uses data previously collected and does not impose any form of intervention, no formal Consent to Release Information form and no Institutional Review Board/Independent Ethics Committee (IRB /IEC) review were required.

Cancerology database French Q1 2020 edition was conducted as part of the commitment of the MR-004 reference methodology which covers the data processing and delivered by the French Data Protection Authority (CNIL) with the authorization number n°2204473 v0. Other Cancerology database editions (French 2021, German 2021, Italian 2020, Spanish 2020) were conducted under ISO 20252 quality standards that guarantee the anonymity of the respondents and of their responses.

## **Study design**

Non-interventional cross-sectional retrospective observational database study

## **Primary study design**

Observational

## **Secondary study design**

Cross sectional study

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

Not applicable (retrospective study)

## **Health condition(s) or problem(s) studied**

Frontline transplant-eligible multiple myeloma

## **Interventions**

A non-interventional retrospective observational study will be conducted in France, Germany, Italy and Spain. Patients with a reported diagnosis of multiple myeloma (MM) and on ongoing active treatment will be extracted from the Cancerology MM database editions of each of those four countries (French 2020 & 2021, German 2021, Spanish 2020, and Italian 2020 editions). The Cancerology MM database includes fully anonymized real-world data, composed of serial chart reviews of patients with a diagnosis of MM and on ongoing active treatment.

## **Intervention Type**

Drug

## **Phase**

Not Applicable

## **Primary outcome measure**

Repartition of the treatments received by the patients with frontline transplant eligible multiple myeloma in induction, consolidation, and maintenance phases and evolution of the repartition by year from 2017 to 2019, extracted from the Cancerology MM database editions of those four countries (French 2020 & 2021, German 2021, Spanish 2020, and Italian 2020 editions) collected for the period from diagnosis to date of data collection.

## **Secondary outcome measures**

1. Time from frontline induction to frontline stem cell transplantation extracted from the Cancerology MM database editions of those four countries (French 2020 & 2021, German 2021, Spanish 2020, and Italian 2020 editions) collected for the period from start of frontline induction to frontline stem cell transplantation.
2. Time to next treatment calculated as the duration from the date of initiation of first-line induction to the initiation of the second line of treatment extracted from the Cancerology MM database editions of those four countries (French 2020 & 2021, German 2021, Spanish 2020, and Italian 2020 editions) collected for the period from start of frontline induction to initiation of second line of treatment.
3. Best observed response defined as per standard International myeloma working group response criteria over each previous phase of treatment extracted from the Cancerology MM database editions of those four countries (French 2020 & 2021, German 2021, Spanish 2020, and Italian 2020 editions) collected for the period from diagnosis to date of data collection.
4. Time to best-observed response calculated as the duration from the date of initiation of frontline therapy to the most recent best-observed response date extracted from the Cancerology MM database editions of those four countries (French 2020 & 2021, German 2021, Spanish 2020, and Italian 2020 editions) collected for the period from diagnosis to date of data collection.
5. Duration of therapy calculated as the time from the start of a given treatment to the discontinuation of the same treatment for any reason extracted from the Cancerology MM database editions of those four countries (French 2020 & 2021, German 2021, Spanish 2020, and Italian 2020 editions) collected for the period from diagnosis to date of data collection.
6. Treatment-free interval calculated as the time from the discontinuation of first-line therapy to the initiation of second-line therapy extracted from the Cancerology MM database editions of those four countries (French 2020 & 2021, German 2021, Spanish 2020, and Italian 2020 editions) collected for the period from discontinuation of first-line therapy to initiation of second line of treatment.
7. Minimal residual disease based on physician clinical judgement extracted from the Cancerology MM database editions of those four countries (French 2020 & 2021, German 2021, Spanish 2020, and Italian 2020 editions) collected for the period from diagnosis to date of data collection.

### **Overall study start date**

01/06/2021

### **Completion date**

31/08/2021

## **Eligibility**

### **Key inclusion criteria**

Study population 1 (ongoing FLTE MM population):

1. Being on an ongoing frontline therapy line
2. Being considered either fit for transplant at initial diagnosis, or planned on transplant while on frontline therapy, or having already been transplanted while on frontline therapy

Study population 2 (previous FLTE MM population):

1. Being on an ongoing relapse or refractory multiple myeloma therapy line

2. Having received a previous frontline therapy line
3. Being considered either fit for transplant at initial diagnosis, or having already been transplanted while on frontline therapy

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

400 (100 per country)

**Total final enrolment**

804

**Key exclusion criteria**

Study population 1 (ongoing FLTE MM population):

1. Receiving the ongoing frontline therapy as part of a randomized controlled trial or early access program

Study population 2 (previous FLTE MM population):

1. Having initiated the frontline induction prior to 2017

**Date of first enrolment**

01/01/2020

**Date of final enrolment**

20/07/2021

**Locations****Countries of recruitment**

France

Germany

Italy

Spain

**Study participating centre**

University hospitals, Cancer Centre/oncological reference centre, General/Non-university hospital, Private hospital/clinic

France

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# Sponsor information

## Organisation

Kantar Health (France)

## Sponsor details

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## Sponsor type

Industry

# Funder(s)

## Funder type

Industry

## Funder Name

Janssen EMEA

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

## Intention to publish date

01/11/2022

## Individual participant data (IPD) sharing plan

The participant-level data are proprietary of Kantar Health and Kantar Health is not allowed to share them publicly. The data are stored on a secured server of Kantar Health.

## IPD sharing plan summary

Not expected to be made available