

# Symptom Online Monitoring (SYMON)

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Study

Planned

## Administrative details

### EU PAS number

EUPAS103405

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### Study ID

103406

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### DARWIN EU® study

No

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### Study countries

 Austria

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### Study status

Planned

## Research institutions and networks

### Institutions

# Tirol Kliniken

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

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Institution

## Contact details

### Study institution contact

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Study contact

[wolfgang.willenbacher@tirol-kliniken.at](mailto:wolfgang.willenbacher@tirol-kliniken.at)

### Primary lead investigator

Wolfgang Willenbacher

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 27/01/2023

Actual: 31/01/2023

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### Study start date

Planned: 01/05/2023

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## Date of final study report

Planned: 01/12/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GSK

## Study protocol

[eSymon protocol\\_V2\\_2022\\_06\\_02 final.pdf](#) (389.04 KB)

## Regulatory

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

No

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Other

**If 'other', further details on the scope of the study**

Quality of Life

**Main study objective:**

We propose that patients' treatment of relapsed refractory Multiple Myeloma (RRMM) with Belantamab-Mafodotin (BM) can be optimized using an individualized web-based symptom control and side effects management tool, focusing, but not exclusively, on ocular complaints.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Observational study

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(L01FX15) belantamab mafodotin

belantamab mafodotin

## Population studied

## **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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## **Estimated number of subjects**

25

## **Study design details**

### **Data analysis plan**

We propose the setup of a patient portal to monitor patients HRQOL and, more specifically, their ocular symptoms during treatment with BM. The patient portal will be based on the Computer-based Health Evaluation Software (CHES), which is currently the software basis for the AMR. All eligible patients will be given access to the patient portal and asked to complete regularly scheduled PROs. For this proposal, the AMR can capitalize from existing projects and scientific expertise, which have been completed and collected in the past: The implementation of PROs in the AMR have been previously described by Sztankay and colleagues 14. The study showed the high level of integration of electronic PROs in the registry and the minimal addition to HCPs workload. The usage of ePROs for screening purposes (psycho-oncological screening) have also been described by Lehmann and colleagues 15. Finally, the current configuration of the patient portal have also been evaluated 16.

## **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)

[Disease registry](#)

## 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