# MS100070_0031: Non-interventional cohort registry study to assess characteristics and management of patients with Merkel Cell Carcinoma in Germany (MCC-TRIM)

**First published:** 28/08/2018

**Last updated:** 01/04/2026

Study Finalised

## Administrative details

**EU PAS number**

EUPAS25338

**Study ID**

34181

**DARWIN EU® study**

No

**Study countries**

☐ Germany

**Study description**

This is a 5-year non-interventional (observational), longitudinal, multi-site cohort registry study focusing on various epidemiological and clinical aspects to be assessed in patients diagnosed with MCC in Germany. The design is an open cohort study design, with dynamic, renewed sampling, allowing for each eligible patient to have the same probability to be included throughout the inclusion period.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Merck Healthcare KGaA

Germany

**First published:** 26/02/2024

**Last updated:** 27/03/2026

Institution | Pharmaceutical company

# Contact details

**Study institution contact**

Communication Center Merck KGaA

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Study contact

service@merckgroup.com

**Primary lead investigator**

Communication Center Merck KGaA

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Actual: 21/08/2017

**Study start date**

Actual: 29/04/2019

**Date of final study report**

Actual: 27/11/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Merck KGaA

## Regulatory

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

Yes

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

EU RMP category 3 (required)

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

**Study design:**

This was a 5-year non-interventional (observational), longitudinal, multi-site cohort study

**Main study objective:**
Enlarge ADO MCC Registry by collecting additional data on treatment patterns, comorbidities, concomitant treatments, effectiveness and safety outcomes, HRU and biomarker Information.
This study aims to identify and describe population of MCC patients, their treatment and outcomes in a real-world settings in Germany.

## Study Design

**Non-interventional study design**
Cohort

## Study drug and medical condition

**Medicinal product name**
BAVENCIO

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**Study drug International non-proprietary name (INN) or common name**
AVELUMAB

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**Anatomical Therapeutic Chemical (ATC) code**
(L01FF04) avelumab
avelumab

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**Medical condition to be studied**

Skin cancer

**Additional medical condition(s)**

Merkel cell carcinoma

# Population studied

**Short description of the study population**

Patients were recruited based on a diagnosis of MCC only (all stages and ages), irrespective of treatment and MCC diagnosis tool utilized, from study start (30 April 2019) until 30 September 2023

**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)

**Special population of interest**

Immunocompromised

**Estimated number of subjects**

1000

# Study design details

**Setting**

The study population was recruited by healthcare providers (HCPs) participating in ADOREG, mainly dermato
oncologists, treating and managing patients with MCC in Germany

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**Outcomes**

In patients diagnosed with MCC in Germany

• Patient and tumor characteristics

• Background prevalence rates

• MCC-related treatments for all types and lines of therapy since initial diagnosis of MCC

• Relevant common comorbidities in patients with metastatic stage disease

• Concomitant medications

• Disease outcomes by means of response and survival analyses

• Safety events of interest

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**Data analysis plan**

All statistical analysis will be done using SAS version 9.4 or higher. For categorical variables, summary tabulations of number and percentage within each category (with a category for missing data) of parameter will be presented. For continuous variables, mean, median, standard deviation, minimum and maximum values will be given. All time-to-event analyses will be performed by using Kaplan-Meier methods including calculation of median survival times and 95% confidence intervals (CIs).

Safety analysis will mainly involve assessment of incidence rates (e.g. fatal and nonfatal ADRs, rate of immune-related ADRs).

In addition, as this is an open cohort, accumulation of evidence will continue over the study duration. Data will be analyzed every 6 months as information from more patients is accumulated over the 5-year study period.

The study sponsor will also be able to perform ad hoc queries using the cohort data throughout the duration of the study period of 5 years.

# Documents

**Study report**

ms100070_0031-csr_Redacted.pdf (1.94 MB)

# 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

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No