Real-World Treatment Patterns and Clinical Outcomes of BRAF V600-Mutant Metastatic Melanoma Patients Treated at Academic Oncology Centers in the United States

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Administrative details

EU PAS number

EUPAS100000307

Study ID

100000307

DARWIN EU® study

No

Study countries

United States

Study description

The overarching aim of this study is to describe the real-world characteristics, treatment patterns, and clinical outcomes of patients with BRAF V600-mutant MM presenting for care at academic oncology centers in the US from January 1, 2018 to June 30, 2024 (or the most recent date of data availability.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

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Study contact

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Primary lead investigator Kristina Chen

Study timelines

Date when funding contract was signed Actual: 04/04/2023

Study start date Planned: 18/11/2024

Data analysis start date Planned: 06/12/2024

Date of final study report Planned: 20/06/2025

Sources of funding

• Pharmaceutical company and other private sector

Study protocol

C4221039_RW Treatment Patterns and Clinical Outcomes in BRAF+ MM_Study Protocol_V1.0_17Oct2024_REDACTED.pdf(1.72 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Data collection methods:

Secondary use of data

Study design:

A non-interventional (NI) longitudinal cohort design will be employed for this study.

Deidentified patient data collected retrospectively from academic oncology centers will be used to address all study objectives.

Study Design

Non-interventional study design

Cohort

Population studied

Age groups

Adult and elderly population (\geq 18 years)

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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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