

# Real-world effectiveness of dabrafenib and trametinib in patients with BRAF-positive melanoma treated in routine Bulgarian clinical practice

**First published:** 06/05/2025

**Last updated:** 24/07/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000567

### Study ID

1000000567

### DARWIN EU® study

No

### Study countries

☐ Bulgaria

### Study description

# Real-World Data Analysis of BRAF-Targeted Melanoma Therapy Compared to Clinical Trials Using Danny Platform

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### Sqilline Health

☐ Bulgaria

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

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

**Institution**

**Non-Pharmaceutical company**

The Bulgarian National Council on Prices and  
Reimbursement of Medicinal Products (NCPRMP)

### Contact details

#### Study institution contact

Daniel Penchev info@sqilline.com

**Study contact**

**Primary lead investigator**

Alexandra Savova

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 20/03/2023

Actual: 20/03/2023

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**Study start date**

Planned: 01/01/2018

Actual: 01/01/2018

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**Data analysis start date**

Planned: 07/09/2023

Actual: 07/09/2023

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**Date of final study report**

Planned: 18/12/2024

Actual: 18/12/2024

## Sources of funding

- No external funding

## Regulatory

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

Yes

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

Not applicable

## Other study registration identification numbers and links

Real-world effectiveness of dabrafenib and trametinib in patients with BRAF-pos...

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Study design:**

To assess the real-world effectiveness of dabrafenib and trametinib in patients with BRAF-positive malignant melanoma in a real-world setting.

Compare outcomes, including overall survival (OS) and progression-free survival (PFS), to pivotal clinical trials (COMBI-d and COMBI-v).

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

TAFINLAR

MEKINIST

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

DABRAFENIB

TRAMETINIB

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**Anatomical Therapeutic Chemical (ATC) code**

(L01EC02) dabrafenib

dabrafenib

(L01EE01) trametinib

## **Medical condition to be studied**

Malignant melanoma

## Population studied

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

The study analyzed real-world data (RWD) consisting of 335 patients who were treated with dabrafenib and trametinib from clinical practice between 2018 and 2022.

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### **Age groups**

- **In utero**
- **Paediatric Population (< 18 years)**
  - Neonate
    - Preterm newborn infants (0 – 27 days)
    - Term newborn infants (0 – 27 days)
  - Infants and toddlers (28 days – 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

## Study design details

## Comparators

COMBI-d: comparing the combination of dabrafenib and trametinib to dabrafenib.

COMBI-v: comparing the combination of dabrafenib and trametinib to vemurafenib.

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## Outcomes

### Clinical Outcomes

Progression-Free Survival (PFS). The median PFS based on RWD is 16.1 (95% CI: NC-NC) months in comparison to 9.3 months from COMBI-d trial and 17.0 (95% CI: NC-NC) months vs. 11.4 months from COMBI-v trial.

Overall Survival (OS). In comparison to COMBI-d, RWD outcomes were overall more favorable: OS for RWD was consistently higher than RCT over the first 24 months. Similarly, in comparison to COMBI-v, RWD outcomes were more favorable: OS was close to or higher than the RCT.

Clinical Benefit Rates (CBR) were comparable: RWD is 84.6% (95% CI: 77.9–89.5) vs. 92% for COMBI-d and 90% for COMBI-v.

## Documents

### Study publications

[Real-world effectiveness of dabrafenib and trametinib in patients with BRAF-pos...](#)

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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 source(s)

Danny Platform

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### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Yes

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### Check completeness

Yes

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### Check stability

Yes

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## **Check logical consistency**

Yes

# Data characterisation

## **Data characterisation conducted**

Yes

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## **Data characterisation moment**

after data extraction