

# Reporting and Analysis Plan - ECHO Analyses From Randomized Controlled Trials of Dabrafenib to Evaluate the Potential for Cardiac Valve Abnormalities (201709)

**First published:** 25/08/2014

**Last updated:** 18/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS7313

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### Study ID

40754

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### DARWIN EU® study

No

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### Study countries

 United States

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## Study description

This meta-analysis supported an FDA post-marketing requirement (PMR) to further investigate independently reviewed echocardiogram (ECHO) results for subjects treated with dabrafenib, either as monotherapy or in combination with other anti-cancer therapies on randomized controlled clinical trials. These analyses evaluated the potential for cardiac valve abnormalities in patients treated with dabrafenib based on preclinical findings. The study was cancelled with no patients.

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### Novartis Pharmaceuticals

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

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

Institution

## Contact details

### Study institution contact

Clinical Disclosure Officer Clinical Disclosure Officer  
trialandresults.registries@novartis.com

### Study contact

[trialandresults.registries@novartis.com](mailto:trialandresults.registries@novartis.com)

### Primary lead investigator

Clinical Disclosure Officer Clinical Disclosure Officer

### Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 17/09/2013

Actual: 17/09/2013

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### Study start date

Planned: 17/09/2013

Actual: 17/09/2013

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### Date of final study report

Planned: 20/09/2021

Actual: 17/09/2013

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Novartis

# Study protocol

[gsk2118346-rap-cardiacvalve-redact.pdf](#) (196.56 KB)

## Regulatory

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

Yes

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

Non-EU RMP only

## Other study registration identification numbers and links

CDRB436A2401

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Other

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

Meta-analysis

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The objective of this analysis is to fully describe the results of the independently reviewed ECHO data of subjects treated with dabrafenib.

## Study Design

**Non-interventional study design**

Systematic review and meta-analysis

## Study drug and medical condition

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

DABRAFENIB

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**Medical condition to be studied**

Metastatic malignant melanoma

## Population studied

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

Subjects treated with dabrafenib, either as monotherapy or in combination with other anti-cancer therapies on randomized controlled clinical trials

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### **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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### **Special population of interest**

Other

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### **Special population of interest, other**

Metastatic malignant melanoma patients

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### **Estimated number of subjects**

500

## **Study design details**

### **Data analysis plan**

All analyses of the independently reviewed ECHO data will use the Safety population (SAFETY), which comprises all randomized subjects who received at least one dose of study medication and will be based on the actual treatment received if this differed from that to which the subject was randomized. All analyses will be presented by treatment arm (e.g. dabrafenib monotherapy, dabrafenib plus trametinib, DTIC). All programming will be performed using

SAS\* version 9.1.3 or greater and S-Plus version 7.0 or higher in a UNIX+ environment. All data analyses and tables, listings, and figures will use the formats in the IntegratedData Standards Library (IDSL), unless there is no standard for a particular analysis. Any non-standard data displays will follow the general format of the IDSL and Therapeutic Standards Team (TST) data displays to the extent possible.

## 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), other**

BRF113683, MEK115306, MEK116513, BRF115532

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#### **Data sources (types)**

[Other](#)

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#### **Data sources (types), other**

Phase III randomized studies

### 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