

# PGx447:Exploratory genetic analysis of pazopanib (GW786034) related diarrhea in patient with RCC(VEG102616,VEG105192,VEG107769) (116054)

**First published:** 02/04/2014

**Last updated:** 28/04/2021

Study

Finalised

## Administrative details

### EU PAS number

EUPAS6234

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### Study ID

40739

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study status

Finalised

## Research institutions and networks

### Institutions

#### GlaxoSmithKline (GSK)

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

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Institution

### Contact details

#### Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure  
Advisor Pharma.CDR@gsk.com

Study contact

[Pharma.CDR@gsk.com](mailto:Pharma.CDR@gsk.com)

#### Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure  
Advisor

Primary lead investigator

### Study timelines

**Date when funding contract was signed**

Planned: 08/07/2011

Actual: 08/07/2011

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**Study start date**

Planned: 10/11/2011

Actual: 10/11/2011

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**Date of final study report**

Planned: 30/09/2012

Actual: 22/02/2012

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

## Study protocol

[veg116054-reporting-and-analysis-plan-redact.pdf](#) (243.24 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)?**

EU RMP category 3 (required)

## Methodological aspects

### Study type

#### Study type list

**Study topic:**

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**

Pharmacogenetic study

**Data collection methods:**

Primary data collection

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**Main study objective:**

The objective of this analysis is to investigate if genetic markers from 38 candidate genes or other markers from across the genome are associated with incidence of diarrhoea in RCC patients treated with pazopanib in studies VEG102616, VEG105192 and VEG107769.

### Study Design

## **Non-interventional study design**

Other

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## **Non-interventional study design, other**

Pharmacogenetic study

# Study drug and medical condition

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

PAZOPANIB

# Population studied

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

The genetic analysis population will consist of subjects enrolled in clinical studies VEG102616, VEG105192, and VEG107769 who provided written informed consent for genetic research, provided a blood sample for genotyping and were successfully genotyped for at least one of the genetic markers under study, have valid phenotype data and pass subject QC.

- a. Subject number includes only those who received pazopanib.
  - b. Subjects provided informed consent and a blood sample for pharmacogenetic research. The clinical data used in this analysis were from the April 2008 data cut-off for VEG102616 and the May 2008 data cut-off for VEG105192 and VEG107769.
  - c. VEG107769 was an open-label extension to VEG105192 providing the option for patients who developed progressive disease while on placebo to receive pazopanib treatment.
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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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## Estimated number of subjects

397

# Study design details

## Outcomes

The primary endpoint is the diarrhoea outcome status defined as case or control, The secondary endpoint is diarrhoea toxicity grade levels from 1 to 5 and grade 0 for the controls, defined as an ordinal categorical variable.

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## Data analysis plan

The Case-Control analyses will be performed on the binary outcome measure (diarrhoea status), using logistic regression analysis, the ordinal data analyses will be performed on ordinal categorical diarrhoea toxicity grade levels, using proportional odds model, if the marker meets the p-value threshold for suggestive evidence in the primary analysis.

# Documents

## Study results

[116054 results summary.pdf](#) (118.36 KB)

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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 sources (types)

Other

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### Data sources (types), other

Prospective patient-based data collection

## 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