

# Votrient liver data meta-analysis of phase II and III RCC and STS studies (200277)

**First published:** 03/04/2014

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS6242

### Study ID

18181

### DARWIN EU® study

No

### Study countries

United States

### 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: 13/03/2013

Actual: 13/03/2013

**Study start date**

Planned: 07/04/2013

Actual: 07/04/2013

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**Date of final study report**

Planned: 23/05/2013

Actual: 23/05/2013

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

## Study protocol

[200277-meta-analysis-plan-redact.pdf](#) (157.39 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)?**

Not applicable

## 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**

Meta-analysis

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The primary objective of these analyses will be to characterise the liver safety profile of pazopanib in subjects with locally recurrent and/or metastatic renal cell carcinoma or advanced or recurrent soft tissue sarcoma.

## 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**

PAZOPANIB

## Population studied

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

Meta-analysis of 1500 pazopanib treated patients from phase II and III 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**

Hepatic impaired

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### **Estimated number of subjects**

1500

## **Study design details**

### **Data analysis plan**

A summary of liver re-challenges, adaptations and recovery will be provided. The re-challenge is defined as an ALT elevation, followed by treatment interruption and subsequently an ALT value of Grade 1 or below on or prior to re-starting study treatment, where the ALT elevation means  $ALT > 3 \times ULN$  during on-therapy window and  $\leq 3 \times ULN$  at baseline. The adaptation is defined as an ALT elevation followed by an ALT assessment returning to baseline grade or below without any dose interruption between the ALT elevation and normalisation. Recovery is defined as ALT Grade 1 or below for 2 consecutive visits or Grade 1 or below for one visit if subject discontinued and no subsequent ALT data are available.

## **Documents**

## Study results

[Synop-200277.pdf \(109.16 KB\)](#)

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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**

Unknown