

# Votrient Liver Data Meta-analysis (200276)

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

**Last updated:** 29/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS6229

### Study ID

16867

### DARWIN EU® study

No

### Study countries

☐ United States

### Study status

Finalised

## Research institutions and networks

### Institutions

# GlaxoSmithKline (GSK)

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

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

**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: 01/04/2013

Actual: 01/04/2013

---

### Study start date

Planned: 01/04/2013

Actual: 01/04/2013

---

### **Date of final study report**

Planned: 30/04/2014

Actual: 30/07/2014

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

## Study protocol

[200276-metaanalysis-redact.pdf](#)(329.63 KB)

## Regulatory

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

No

---

### **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

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Other

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

Meta-analysis

**Data collection methods:**

Secondary use of data

---

**Main study objective:**

To characterize pazopanib-induced liver toxicity and to explore potential predictive and/or prognostic factors for pazopanib-induced liver events and risk factors for rechallenge failure.

## 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

Patients from US suffering from pazopanib-induced liver toxicity.

---

### 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)

---

### Special population of interest

Hepatic impaired

---

### Estimated number of subjects

2080

## Study design details

### Data analysis plan

Data will be summarised by indication and also by the peak ALT level during the first ALT elevation >3xULN (>3-5xULN, >5-8xULN, >8-20xULN and >20xULN).

This is defined as the peak ALT value from the initial elevation >3xULN until recovery. Recovery is defined as ALT returning to 2.5xULN or below for two consecutive tests or dropping to 2.5xULN or below once after study treatment discontinuation with no further data available. Recovery also includes those cases where dose was interrupted after an ALT>3xULN event, then ALT returned to 2.5xULN or below with only one test and subject was re-challenged before their next ALT test.

## Documents

## Study results

[gsk-200276-clinical-study-report-redact.pdf](#)(1.19 MB)

---

## 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](#)

---

### 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

---

**Check completeness**

Unknown

---

**Check stability**

Unknown

---

**Check logical consistency**

Unknown

Data characterisation

**Data characterisation conducted**

Unknown