

# Drug Utilization Study of ZALTRAP® (aflibercept) Using European Databases (Zaltrap Utilization Study)

**First published:** 05/12/2013

**Last updated:** 25/06/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS5365

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### Study ID

16787

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### DARWIN EU® study

No

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### Study countries

 France

 Germany

 Italy

 Spain

## Study description

During the registration application with EMA for aflibercept to be marketed in the EU, Sanofi proposed a three-year drug utilization study (DUS) using European databases as part of the post-approval commitments. The primary objectives of the proposed DUS are to monitor ZALTRAP use in cancer patients including potential off-label use and evaluate the potential for intravitreal use.

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## Study status

Finalised

# Research institutions and networks

## Institutions

[Real World Evidence Solutions, IMS Health](#)

 France

**First published:** 06/09/2011

**Last updated:** 20/08/2024

**Institution**

Other

## Contact details

### Study institution contact

Vernon Schabert [VSchabert@us.imshealth.com](mailto:VSchabert@us.imshealth.com)

**Study contact**

[VSchabert@us.imshealth.com](mailto:VSchabert@us.imshealth.com)

### **Primary lead investigator**

Vernon Schabert

**Primary lead investigator**

## Study timelines

### **Date when funding contract was signed**

Planned: 30/08/2013

Actual: 16/10/2013

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### **Study start date**

Planned: 01/01/2013

Actual: 01/01/2013

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### **Data analysis start date**

Planned: 02/06/2014

Actual: 02/06/2014

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### **Date of interim report, if expected**

Planned: 30/11/2014

Actual: 30/11/2014

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

Planned: 30/11/2016

Actual: 30/11/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Sanofi

## Study protocol

[Zaltrap DUS Protocol Final\\_revision.pdf](#) (330.09 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)?**

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:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

- To evaluate the frequency distribution of cancer type(s) among patients who receive treatment containing ZALTRAP in the five largest national markets in Europe (EU5): United Kingdom (UK), France, Germany, Italy, and Spain.
- To describe different treatment combinations among patients who receive therapy containing ZALTRAP in the EU5.
- To evaluate the proportion of ZALTRAP patients with observed intravitreal use in England.

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Medicinal product name**

ZALTRAP

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

AFLIBERCEPT

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## **Anatomical Therapeutic Chemical (ATC) code**

(L01XX44) aflibercept

aflibercept

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## **Medical condition to be studied**

Colorectal neoplasm

Colorectal cancer metastatic

## **Population studied**

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

Patients from the EU5 for whom the physician reported the receipt of at least one dose of ZALTRAP, as a current therapy.

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### **Age groups**

- Term newborn infants (0 - 27 days)
  - Infants and toddlers (28 days - 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
  - 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

Immunocompromised

Pregnant women

Renal impaired

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### **Estimated number of subjects**

100

## Study design details

### **Data analysis plan**

Descriptive statistics will be provided

## Documents

### **Study results**

[Zaltrap DUS Study Final Report.pdf](#) (305.12 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 source(s)**

HTI - Hospital Treatment Insights

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**Data source(s), other**

IMS Oncology Analyzer, United Kingdom

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**Data sources (types)**

[Other](#)

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**Data sources (types), other**

The IMS Oncology Analyzer™ (OA) is a quarterly structured survey of treated prevalence for over 25 leading solid tumors and hematological malignancies.

## 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