

# An Observational study of Avastin (Bevacizumab) in combination with chemotherapy for treatment of metastatic or locally advanced and unresectable colorectal cancer and locally advanced or metastatic non-small cell lung cancer (excluding predominant squamous cell histology) (ARIES)

**First published:** 28/09/2012

**Last updated:** 28/09/2012

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS3004

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### Study ID

3005

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**DARWIN EU® study**

No

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### Study countries

 United States

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### Study description

This is an observational study designed to follow patients with metastatic or locally advanced and unresectable CRC, locally advanced or metastatic NSCLC (excluding predominant squamous histology) who are receiving Avastin in combination with first-line chemotherapy. Second-line metastatic CRC patients are also eligible. Patients who started their Avastin containing therapy <3 months prior to enrollment are eligible.

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### Study status

Ongoing

## Research institutions and networks

### Institutions

**Genentech**

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

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**Institution**

Other

### Contact details

### **Study institution contact**

Darshan Dalal dalal.darshan@gene.com

Study contact

[dalal.darshan@gene.com](mailto:dalal.darshan@gene.com)

### **Primary lead investigator**

Darshan Dalal

Primary lead investigator

## Study timelines

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

Actual: 05/09/2006

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### **Study start date**

Actual: 10/11/2006

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

Planned: 31/01/2013

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Genentech, Inc.

## Regulatory

## Was the study required by a regulatory body?

No

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Main study objective:**

This is an observational study designed to evaluate the effectiveness and safety of patients with metastatic or locally advanced and unresectable CRC, locally advanced or metastatic NSCLC (excluding predominant squamous histology) who are receiving Avastin in combination with first-line chemotherapy. Second-line metastatic CRC patients are also eligible.

## Study Design

#### **Non-interventional study design**

Cohort

## Study drug and medical condition

## Medicinal product name

AVASTIN

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## Medical condition to be studied

Colorectal cancer

Non-small cell lung cancer

## Population studied

### 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

4000

## Study design details

### Outcomes

Effectiveness outcome measures (which include progression-free survival, response rate, overall survival) Safety outcome measures

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### Data analysis plan

Patient demographics and baseline characteristics will be described using summary statistics. Effectiveness and safety outcomes will be summarized overall (safety only), by tumor type (CRC and NSCLC), and by class of

chemotherapy. The effectiveness analyses for each indication will include Kaplan-Meier estimates of median PFS and overall survival (OS) and presented with 95% confidence intervals (CIs). Multivariable Cox proportional hazard regression models, adjusting for baseline covariates will also be performed. For CRC patients, PFS will be summarized separately for first-line and second-line patients. For safety analyses, descriptive summaries on protocol-specified BV-associated adverse events (AEs) over the entire follow-up will be presented. Incidence proportions and their exact 95% confidence intervals will be reported.

## 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