

# Safety and Effectiveness of Ramucirumab in Patients with Advanced Gastric Cancer in the European Union and North America: A Prospective Observational Registry (I4T-MC-JVDD)

**First published:** 30/11/2015

**Last updated:** 19/04/2022

Study

Finalised

## Administrative details

### EU PAS number

EUPAS9400

### Study ID

46805

### DARWIN EU® study

No

### Study countries

- Austria
- Belgium

- France
- Germany
- Italy
- Spain
- Switzerland
- United States

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### **Study description**

This is a prospective, non-interventional, non-comparative, observational cohort study / registry in the EU and North America. The overall study objective is to evaluate the safety and effectiveness of ramucirumab administered as monotherapy or in combination therapy for second-line treatment of adult patients with advanced gastric cancer under real-world disease conditions.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

#### Quintiles

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

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**Institution**

## Contact details

**Study institution contact**

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**Primary lead investigator**

Yu-Jing Huang

[Primary lead investigator](#)

## Study timelines

**Date when funding contract was signed**

Planned: 24/02/2015

Actual: 24/02/2015

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**Study start date**

Planned: 15/12/2015

Actual: 09/12/2015

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**Date of interim report, if expected**

Actual: 24/05/2019

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**Date of final study report**

Planned: 15/12/2021

Actual: 10/12/2021

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## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company

## Study protocol

[RAM JVDD PASS \(v2.0\).pdf \(537.58 KB\)](#)

## 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

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

The overall study objective is to evaluate the safety and effectiveness of ramucirumab under real-world disease conditions in the Europe and North America

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

RAMUCIRUMAB

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**Medical condition to be studied**

Gastric cancer stage IV

## Population studied

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

This study will include a cohort of approximately 600 adult patients from the EU and North America with advanced gastric cancer or GEJ adenocarcinoma whose disease has progressed after prior chemotherapy and who are treated with ramucirumab alone or in combination therapy as second-line therapy under real-world disease conditions. The decision to initiate use of ramucirumab is made independently by the participant and their health care provider and is not mandated by the study design or protocol.

### **Inclusion Criteria**

- [1] Adult patients (age  $\geq$  18 years at enrolment) with advanced gastric cancer or GEJ adenocarcinoma whose disease has progressed after prior chemotherapy.
- [2] Patients who initiate ramucirumab treatment either as a single agent or in combination with chemotherapy.
- [3] Patients who have been fully informed and have given written consent to the use of the needed information to be part of the observational study.

### **Exclusion Criteria**

- [4] Patients who have received more than 1 line of chemotherapy for advanced gastric cancer or GEJ adenocarcinoma.
- [5] Patients concurrently participating in any study including administration of any investigational drug (including ramucirumab) or procedure (including survival follow-up).

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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**

Renal impaired

Hepatic impaired

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## **Estimated number of subjects**

600

# **Study design details**

## **Outcomes**

To describe the safety of ramucirumab administered as monotherapy or in combination therapy for second-line treatment of adult patients with advanced gastric cancer under real-world disease conditions in the Europe and North America, To describe the safety profile in the following subgroups: Elderly patients, patients with cardiac comorbidities, hepatic impairment, and renal impairment. To describe the effectiveness of ramucirumab administered as monotherapy or in combination therapy for second-line treatment of adult patients with advanced gastric cancer under real-world disease conditions in the Europe and North America

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## **Data analysis plan**

This population includes all patients who have given informed consent and received at least 1 dose of ramucirumab alone or in combination therapy as second-line therapy. Adverse events will be collected, coded, and categorized using the Medical Dictionary for Regulatory Activities (MedDRA). For the primary objective (that is safety), a descriptive analysis will be conducted to evaluate

the safety of ramucirumab. Categorical measures will be summarised as counts and percentages, while continuous measures will be summarised using mean, median, standard deviation, and range. For effectiveness outcomes, overall survival and progression-free survival, Kaplan-Meier estimates (including curves) will be generated. The median and survival rates at given time points (eg, 3, 6, 9, 12 months) will be computed together with their 95% CIs using the Kaplan-Meier method. Best tumour response, treatment patterns, healthcare resource utilisation, and supportive care will be summarised descriptively

## Documents

### Study results

[I4T-MC-JVDD PASS Final Study Report\\_Redacted.pdf \(5.37 MB\)](#)

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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

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## Data characterisation

**Data characterisation conducted**

No