# ChaRactErization of patients following aCute venous thrOmboembolism (VTE) and assessment of safety and effectiveness of dabigatran etexilate (DE) in the tReatment and secondarY prevention of acute deep vein thrombosis (DVT) and pulmonary embolism (PE) in comparison to vitamin K antagonist (VKA) in routine clinical practice - RE-COVERY DVT/PE

**First published:** 21/10/2015

**Last updated:** 14/10/2026

Study Finalised

## Administrative details

**EU PAS number**

EUPAS11368

**Study ID**

34224

**DARWIN EU® study**

No

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**Study countries**

- Argentina
- Austria
- Belgium
- Brazil
- Bulgaria
- Canada
- Chile
- Colombia
- Ecuador
- Egypt
- Germany
- Greece
- Hungary
- Italy
- Korea, Republic of
- Latvia
- Lebanon
- Malaysia
- Mexico
- Netherlands
- New Zealand
- Peru
- Philippines
- Poland
- Portugal
- Romania

- Russian Federation
- Saudi Arabia
- Serbia
- Slovakia
- Slovenia
- Sweden
- Thailand
- Türkiye
- United Arab Emirates
- United Kingdom
- United States
- Viet Nam

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**Study description**

RE-COVERY is a large, multi-national, multi-center non-interventional study based on new data collection. The study will enroll and characterize patients within 30 days of being diagnosed with an acute DVT and/or PE. The study has two main objectives. Objective 1 willcharacterize the DVT / PE patient population. All patients with a DVT and/or PE will be enrolled for cross-sectional characterization of the VTE patient population. Objective 2 will compare the safety and effectiveness of dabigatran etexilate regimens for treatment of VTE in comparison to VKA regimens. Patients treated with dabigatran etexilate or VKA will befollowed up for the occurrence of outcome events for up to one year.

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**Study status**

Finalised

# Research institutions and networks

## Institutions

## Boehringer Ingelheim

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

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

Institution

# Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Boehringer Ingelheim

Primary lead investigator

# Study timelines

**Date when funding contract was signed**

Planned: 15/09/2014

Actual: 15/09/2014

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**Study start date**

Planned: 18/01/2016

Actual: 03/02/2016

**Date of final study report**
Planned: 17/04/2020

Actual: 18/02/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Boehringer Ingelheim

## Study protocol

1160_188_REDACTED PROTOCOL.pdf (796.73 KB)

## Regulatory

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

No

**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Other study registration identification numbers and links

1160.188

# Methodological aspects

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Study design:**

RE-COVERY is a large, multi-national, multi-centre observational study based on new data collection. The study enrolled and characterised patients diagnosed with an acute DVT and/or PE from 229 sites from 5 regions:
Europe, North America, Middle East, Asia and Latin America.

**Main study objective:**

Objective 1: To characterize the DVT/PE patient population including the initial acute event phase.Objective 2: To analyze the safety and effectiveness of dabigatran etexilate regimens in the treatment of DVT and PE over 1 year of follow-up in comparison to a VKA regimen.

# Study Design

**Non-interventional study design**

Cohort

Cross-sectional

# Study drug and medical condition

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

DABIGATRAN ETEXILATE

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**Anatomical Therapeutic Chemical (ATC) code**

(B01AE07) dabigatran etexilate

dabigatran etexilate

(B01AA) Vitamin K antagonists

Vitamin K antagonists

(B01) ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

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**Medical condition to be studied**

Deep vein thrombosis

Pulmonary embolism

# 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**

14.000

# Study design details

**Setting**

Participation of a country required the approval of dabigatran for the VTE indication prior to study initiation within that country. Selected sites withineach country included those physicians (e.g., specialist and general practitioners) and facilities (e.g., general practice offices, specialist offices, hospitals, outpatient care centres and anticoagulation clinics) that reflected the clinical practice within that country.

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**Outcomes**

For Objective 1, the primary outcomes are:-Demographic information (age and gender)-VTE event information (event type and treatment for event)For Objective 2, the primary outcomes are:-Primary safety outcome measure: ISTH Major bleeding-Primary effectiveness outcome measure: symptomatic recurrent VTE including VTE-related mortality, In Objective 2 patients, the secondary outcomes are:-recurrent DVT-recurrent PE-recurrent DVT and PE-VTE-related mortality-all-cause mortality

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**Data analysis plan**

Patient demographics and baseline characteristics will be summarized descriptively. Multivariable regression models and propensity score based methods will be used for the comparative analyses of dabigatran etexilate and VKA patients.

# Documents

**Abstract of study report**

1160-0188_Synopsis.pdf (274.41 KB)

# 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**

No