

# Post marketing surveillance program of Praxbind™ use in (Praxbind™ India PMS program)

**First published:** 10/11/2017

**Last updated:** 17/12/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS21619

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### Study ID

34131

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### DARWIN EU® study

No

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### Study countries

India

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### Study description

The main objective of the Praxbind™ administration surveillance program is to evaluate the prescription patterns of use of Praxbind™ in a clinical practice setting, with special focus on ADRs and fatal AEs. Primary Outcome:-Any suspected ADRs and fatal AEs, with special focus on hypersensitivity and thrombotic event, occurred within 7 days after Praxbind™ administration.

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### Study status

Finalised

## Research institutions and networks

### Institutions

[Boehringer Ingelheim](#)

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**Institution**

[AllMS New Delhi, Sir HN Reliance Foundation  
Hospiat Mumbai, Dr L H Hiranandani Hospital  
Mumbai, St. John's Medical College and Hospital  
Bengaluru, Apollo Hospital Chennai, Medanta, The  
Medicity New Delhi, Batra Hospital and Medical  
Research Centre New Delhi, Sir Ganga Ram](#)

Hospital New Delhi, Holy Family hospital Mumbai,  
Nizams Institute of Medical Sciences Hyderabad

## Contact details

### Study institution contact

Gokhale Partha partha.gokhale@boehringer-ingenelheim.com

Study contact

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### Primary lead investigator

Bondal Sumedh

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 19/07/2017

Actual: 19/07/2017

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### Study start date

Planned: 20/12/2018

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### Data analysis start date

Planned: 19/03/2020

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### Date of final study report

Planned: 20/04/2020

Actual: 06/10/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Boehringer Ingelheim India Pvt. Ltd.

## Study protocol

[clinical-trial-protocol-version-02.pdf](#) (462.77 KB)

[non-interventional-study-protocol-version-03.pdf](#) (471.12 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)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

**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:**

Drug utilisation  
Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Study design:**

Multicenter, non-interventional, drug administration surveillance program

**Main study objective:**

The main objective of the Praxbind™ drug administration surveillance program is to evaluate the prescription patterns of use of Praxbind™ in a clinical practice setting, with special focus on ADRs and fatal AEs.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Post Marketing Surveillance

## Study drug and medical condition

**Medicinal product name**

PRAXBIND

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**Medicinal product name, other**

Praxbind™

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

IDARUCIZUMAB

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**Anatomical Therapeutic Chemical (ATC) code**

(V03AB37) idarucizumab

idarucizumab

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**Medical condition to be studied**

Brief resolved unexplained event

## Population studied

**Short description of the study population**

1. Patients treated with Pradaxa® (dabigatran etexilate) capsules with requirement of rapid reversal of the anticoagulant effects of dabigatran:

For emergency surgery/urgent procedures

Or

In life-threatening or uncontrolled bleeding

2. Written informed consent in accordance with International Conference on Harmonization Good Clinical Practice (GCP) guidelines and local legislation and/or regulations.

Exclusion criteria:

Participation in a Praxbind® clinical trial

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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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## Estimated number of subjects

25

# Study design details

## Setting

The study was performed in the Clinical Practice Setting. Participating hospitals had readiness for emergency services and access to Praxbind®.

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## Outcomes

Primary outcomes Any suspected ADRs and fatal AEs, with special focus on hypersensitivity and thrombotic event, occurred within 7 days after Praxbind™ administration. Secondary outcomes Percentage of patients who either received Praxbind™ for emergency surgery/urgent procedures or in life-threatening or uncontrolled bleeding at the end of 2 years.

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## Data analysis plan

All variables will be presented using descriptive statistics (absolute and relative frequencies, means, standard deviations, medians, quartiles, minimum and maximum values, 95% CIs) as appropriate for the nature of the variables (i.e. categorical or continuous).

# Documents

## Abstract of study report

[1321-0023\\_Synopsis.pdf](#) (249.37 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](#)

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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