

# Real World Use, Effectiveness and Safety of Teprotumumab among Thyroid Eye Disease Patients treated in China BOAO Pilot Zone: A Retrospective Cohort Study (20240345)

**First published:** 30/06/2025

**Last updated:** 18/02/2026

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000625

---

### Study ID

1000000625

---

### DARWIN EU® study

No

---

### Study countries

 China

---

### Study status

Ongoing

## Research institutions and networks

# Institutions

## Amgen

 United States

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

**Last updated:** 27/03/2026

Institution

## Contact details

### Study institution contact

Global Development Leader Amgen Inc.  
medinfo@amgen.com

Study contact

[medinfo@amgen.com](mailto:medinfo@amgen.com)

### Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 12/05/2025

Actual: 12/05/2025

---

**Study start date**

Planned: 30/07/2025

Actual: 02/07/2025

---

**Data analysis start date**

Planned: 30/09/2025

Actual: 15/09/2025

---

**Date of final study report**

Planned: 28/02/2026

## Study protocol

[20240345 Protocol-Published Original teprotumumab-trbw redacted.pdf](#) (15.84 MB)

## Regulatory

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

No

---

**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

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Effectiveness study (incl. comparative)  
Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

---

**Main study objective:**

The main objective of this study is to assess proportion of patients with proptosis response as of last intravenous infusion of teprotumumab.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name, other**

Teprotumumab (TEPEZZA®)

---

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

TEPROTUMUMAB

---

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

(L04AG13) teprotumumab

teprotumumab

---

## **Medical condition to be studied**

Graves' disease

---

## **Additional medical condition(s)**

thyroid eye disease

# Population studied

## **Age groups**

- **Adult and elderly population ( $\geq 18$  years)**

- Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly ( $\geq 65$  years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)
- 

## **Estimated number of subjects**

10

# Study design details

## **Outcomes**

Secondary endpoints

- Baseline characteristics
  - Teprotumumab use
  - Proptosis
  - Clinical Activity Score
  - Diplopia
  - Quality of life
  - The incidence of adverse events between the administration of the first dose and 30 days after the last dose of teprotumumab
  - Status of AE of interest up to 6 months after last infusion of teprotumumab
- 

## **Data analysis plan**

All analyses will be descriptive in nature.

## 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), other**

**Data sources (types)**

Electronic healthcare records (EHR)

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Yes

---

**Check completeness**

Yes

---

**Check stability**

Yes

---

**Check logical consistency**

Yes

## Data characterisation

**Data characterisation conducted**

Yes