

# Effectiveness of the Nplate Additional Risk Minimisation Materials Implemented in Australia (20210176)

**First published:** 31/03/2022

**Last updated:** 08/03/2023

Study

Finalised

## Administrative details

### EU PAS number

EUPAS46340

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### Study ID

49211

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### DARWIN EU® study

No

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### Study countries

 Australia

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### Study status

Finalised

## 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: 01/04/2022

Actual: 01/04/2022

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**Study start date**

Planned: 01/04/2022

Actual: 06/04/2022

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**Data analysis start date**

Planned: 01/06/2022

Actual: 01/06/2022

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**Date of final study report**

Planned: 30/11/2022

Actual: 25/01/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[Protocol-Published Original romiplostim 20210176.pdf](#) (2.98 MB)

## Regulatory

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

Yes

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

## 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:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

To assess whether the aRMMs implemented by Amgen Australia are effective in minimizing the risk of medication errors in patients being treated with NPlate by determining usage and utility of the aRMMS and if the incidence of medication errors in Australia has changed.

### Study Design

## **Non-interventional study design**

Other

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## **Non-interventional study design, other**

Online survey

# Study drug and medical condition

## **Medicinal product name**

[NPLATE](#)

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## **Medical condition to be studied**

Thrombocytopenia

# Population studied

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

An online survey of haematologists and haematology nurses who had treated patients with immune thrombocytopenia (ITP) with Nplate for the period of 12 December 2018 to 31 December 2021.

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## **Age groups**

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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**

30

## Study design details

### **Data analysis plan**

This study is analyzing secondary data from the Amgen drug safety database and no safety data will be collected.

## Documents

### **Study results**

[20210176\\_ORSR\\_Abstract\\_Redacted.pdf](#) (269.81 KB)

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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**

Questionnaire for healthcare providers and safety data analysis of data from Amgen drug safety database

## 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