

# TAK-834-4008: Quantitative Testing of Patient and Healthcare Provider Knowledge, Attitudes, and Behavior About NATPARA® (Parathyroid Hormone) for Injection, for Subcutaneous Use (NATPARA KAB)

**First published:** 26/09/2022

**Last updated:** 07/01/2025

Study

Ongoing

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/49588>

### EU PAS number

EUPAS48713

### Study ID

49588

### DARWIN EU® study

No

## Study countries

☐ United States

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## Study description

This main aim of this study is to check level of knowledge and assess attitudes and behaviors of both participants and physicians regarding the risks and safe use of NATPARA. The survey will be done via internet, telephone, or paper and participants will be able to choose the method that is preferred.

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## Study status

Ongoing

# Research institutions and networks

## Institutions

Shire

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

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

Institution

## Contact details

### Study institution contact

Study Contact Shire

Study contact

**Primary lead investigator**

Study Contact Shire

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 01/09/2015

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**Study start date**

Actual: 01/09/2015

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**Date of final study report**

Planned: 31/01/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Shire

## Regulatory

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

Yes

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

Non-EU RMP only

## Other study registration identification numbers and links

NCT05556629 -

<https://clinicaltrials.gov/ct2/show/NCT05556629>,, <https://clinicaltrials.takeda.com/study-detail/7e4fd13264a44033?idFilter=%5B%22TAK-834-4008%22%5D>

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Other

**If 'other', further details on the scope of the study**

Knowledge, Attitude, Behavior Survey

**Main study objective:**

The main aim of this study is to check level of knowledge and assess attitudes and behaviors of both participants and physicians regarding the risks and safe use of NATPARA. The survey will be done via internet, telephone, or paper and participants will be able to choose the method that is preferred.

## Study Design

### **Non-interventional study design**

Other

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

Survey

## Study drug and medical condition

### **Medical condition to be studied**

Hypoparathyroidism

## 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

200

## Study design details

### Outcomes

Number of Participants and Prescribers Providing Correct Responses to Questions, Number of Participants and Prescribers Providing At Least 80 Percent (%) Correct Responses to Each Key Risk Message and who Demonstrated Understanding of Each Key Risk Message

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### Data analysis plan

Data from all respondents who access the survey will be collected. Only data from those survey respondents who were eligible to participate in the survey and answered all questions (“completers”) will be analyzed. Counts and percentages will be calculated for each question/item in the questionnaire. P-values for comparison of how representative the respective survey respondents are of the respective stakeholder population will be obtained from the chi-square test.

## Data management

## Data sources

### Data sources (types)

Other

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### **Data sources (types), other**

The primary source for this study is the Knowledge, Attitudes and Behavioral (KAB) and Risk Evaluation and Mitigation Strategy (REMS) surveys. Survey will be administered via internet, phone, or paper.

## 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