

# Non-interventional study for the generation of long term safety and efficacy data of pasireotide s.c. in patients with Cushing's disease (Post-Authorization Safety Study)

**First published:** 10/12/2012

**Last updated:** 16/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS3199

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### Study ID

39654

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### DARWIN EU® study

No

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### Study countries

 Canada

 Colombia

 France


 Germany

 Israel

 Italy

 Lebanon

 Netherlands

 United Kingdom

 United States

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## Study status

Finalised

## Contact details

### Study institution contact

Mario Maldonado [maldonado.m@recordati.com](mailto:maldonado.m@recordati.com)

**Study contact**

[maldonado.m@recordati.com](mailto:maldonado.m@recordati.com)

### Primary lead investigator

Giovanna Mantovani

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Actual: 10/07/2012

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### Study start date

Planned: 15/02/2013

Actual: 28/03/2013

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### **Date of final study report**

Planned: 26/09/2024

Actual: 19/04/2024

## Regulatory

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

Yes

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

#### Study type list

##### **Study type:**

Non-interventional study

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## Study drug and medical condition

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

(H01CB05) pasireotide

## 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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

### Use of a Common Data Model (CDM)

#### **CDM mapping**

No

### Data quality specifications

#### **Check conformance**

Yes

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#### **Check completeness**

Yes

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#### **Check stability**

Yes

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#### **Check logical consistency**

Yes

## Data characterisation

### **Data characterisation conducted**

Yes