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

Study ID

39654

DARWIN EU® study

No

Study countries

Canada

Colombia

France

Germany

Israel

Italy

Lebanon

Netherlands

United Kingdom

United States

Study status

Finalised

Contact details

Study institution contact

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Study contact

maldonado.m@recordati.com

Primary lead investigator

Giovanna Mantovani

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 10/07/2012

Study start date

Planned: 15/02/2013

Actual: 28/03/2013

Date of final study report

Planned: 26/09/2024

Actual: 19/04/2024

Regulatory

Was the study required by a regulatory body?

Yes

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

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(H01CB05) pasireotide

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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.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

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes