Evaluation of the Physician Education Component of the Ozurdex Risk Management Plan

First published: 17/08/2018

Last updated: 14/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/33655

EU PAS number

EUPAS24861

Study ID

33655

DARWIN EU® study

No

Study countries

☐ France

- [ ] Germany
- [ ] Spain
- [ ] United Kingdom

Study description

The survey objective is to assess the effectiveness of the educational material provided to physicians treating patients with Ozurdex by evaluating the physicians' knowledge and understanding of the key information in the Ozurdex Injector's Guide.

Study status

Finalised

Research institutions and networks

Institutions

RTI Health Solutions (RTI-HS)

- [ ] France
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom
- [ ] United Kingdom (Northern Ireland)
- [ ] United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

William K Mountford

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/11/2017

Actual: 14/11/2017

Study start date

Planned: 15/10/2018

Actual: 08/10/2018

Date of final study report

Planned: 29/03/2019

Actual: 12/03/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Allergan

Study protocol

Riskmgtsystem-Evaluation_Final Protocol_V3.0_15Mar2018_Redacted.pdf
(547.97 KB)

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)

Other study registration identification numbers and links

CMO-EPI-EYE-0522

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The objective of this survey is to assess the effectiveness of the educational material provided to physicians treating patients with Ozurdex by evaluating the physicians’ knowledge and understanding of the key

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Online survey

Study drug and medical condition

Name of medicine

OZURDEX

Population studied

Short description of the study population

Physicians (ophthalmologists and retinal specialists) in France, Germany, Spain, and the UK who have administered an Ozurdex injection to at least one patient in the past 6 months.

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)

Estimated number of subjects

400

Study design details

Outcomes

the goal of the survey is to evaluate the physicians’ knowledge and understanding of the key information in the Ozurdex Injector’s Guide

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Data analysis plan

The analyses will be descriptive in nature and will include a detailed review of responses to individual questions, as well as potential summary measure across

logical groupings of response items.

Documents

Study results

Ozurdex RMM Eval_final study report Abstract.pdf(25.7 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Physician survey

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No