# Ozurdex® (dexamethasone) Implant Risk Management Plan Injector's Guide Assessment Australia

First published: 04/06/2018

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### Administrative details

<b>EU PAS number</b> EUPAS23093		
Study ID		
24504		
DARWIN EU® study		
No		
Study countries		
Australia		

**Study description** 

This annex is provided in order to present a comprehensive assessment of the risk and benefits of OZURDEX® (dexamethasone) 700  $\mu$ g intravitreal implant and to add Australia-specific risk assessment information to the risk management plan (RMP) v8.1

#### **Study status**

Finalised

### Research institutions and networks

### Institutions

So What Research Pty Ltd

### Contact details

#### **Study institution contact**

George Labib CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

### Primary lead investigator

George Labib

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Actual: 29/04/2016

#### **Study start date**

Actual: 20/12/2017

#### Date of interim report, if expected

Actual: 21/12/2017

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

Actual: 29/01/2018

### Sources of funding

• Pharmaceutical company and other private sector

### More details on funding

Allergan

### Study protocol

OZURDEX\_AUSTRALIA\_RMP\_ASA\_v5.3\_RVO-DME-Uveitis\_May2017\_Redacted.pdf (1.22 MB)

# Regulatory

Was the study required by a regulatory body?

Yes

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

# 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 goal of the survey is to evaluate physicians' comprehension of the key risks related to OZURDEX® injection described in the educational materials.

# Study Design

### Non-interventional study design

Other

#### Non-interventional study design, other

Online survey

# Study drug and medical condition

#### **Medicinal product name**

**OZURDEX** 

### Population studied

#### Short description of the study population

Australian Retinal Specialists/Ophthalmologists between 24 November 2017 and 20 December 2017.

#### 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**

20

# Study design details

#### **Outcomes**

To evaluate the effectiveness of the education materials and their effectiveness as a measure to reduce all the specified important identified risks.

#### Data analysis plan

The pass rate as defined in the survey for each individual HCP is a result of at least 80% correct. Therefore, a HCP is defined as passing with 19/23 (approx. 80%) for more correctly answered questions

### **Documents**

#### **Study results**

Ozurdex RMP REPORT FINAL\_29Jan18\_clean\_v3.0\_Redacted.pdf (464.61 KB)

### 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

# 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** 

Unknown