

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

**First published:** 04/06/2018

**Last updated:** 01/04/2024

Study

Finalised

## Administrative details

### EU PAS number

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 µg 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](mailto:CT.Disclosures@abbvie.com)

Study contact

[CT.Disclosures@abbvie.com](mailto: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**

Cross-sectional

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