

# Evaluation of the Effectiveness of Risk Minimisation Measures: A Survey among Health Care Professionals to Assess their Knowledge and Attitudes on Prescribing Conditions of Instanyl® in France and the Netherlands

**First published:** 16/06/2015

**Last updated:** 29/03/2024

Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/16237>

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### **EU PAS number**

EUPAS9924

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### **Study ID**

16237

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### **DARWIN EU® study**

No

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## Study countries

France

Netherlands

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## Study description

A survey of prescribers of Instanyl in France and Netherlands to assess the effectiveness of education materials on safe use of Instanyl.

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## Study status

Finalised

# Research institution and networks

## Institutions

[Real World Evidence Solutions, IMS Health](#)

France

**First published:** 06/09/2011

**Last updated:** 20/08/2024

**Institution**

Other

## Contact details

### Study institution contact

Massoud Toussi

**Study contact**

mtoussi@fr.imshealth.com

## Primary lead investigator

Massoud Toussi

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/03/2015

Actual: 01/03/2015

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### Study start date

Planned: 01/04/2015

Actual: 01/04/2015

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### Data analysis start date

Planned: 01/10/2015

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### Date of final study report

Planned: 01/03/2016

Actual: 16/11/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Takeda Development Centre Europe

## Study protocol

## 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 topic:**

Human medicinal product

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Effectiveness study (incl. comparative)

#### **Data collection methods:**

Primary data collection

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#### **Main study objective:**

The objective of the survey is to measure the proportion of targeted physicians who received, understood and followed the safety information about Instanyl® provided in the updated educational materials.

## Study Design

### **Non-interventional study design**

Cross-sectional

Other

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### **Non-interventional study design, other**

Non-interventional survey

## Study drug and medical condition

### **Name of medicine**

INSTANYL

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### **Medical condition to be studied**

Cancer pain

## Population studied

### **Short description of the study population**

Physicians prescribers, or potential prescribers, of Instanyl® who are targeted for the educational materials.

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### **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)

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### **Estimated number of subjects**

267

## Study design details

### **Data analysis plan**

Continuous variables will be described by the number of valid cases and missing data, mean, standard deviation, median, Q1, Q3, minimum, and maximum. No missing data will be replaced. Categorical variables will be described as the total number and relative percentage per category.

Confidence intervals of 95% will be calculated when relevant. Calculations will first be performed on raw data per specialty, and weighted according to the real proportion of targeted physicians in each country to accurately reflect the population the survey seeks to measure. Possible selection bias will be assessed by comparing the distributions of available characteristics (e.g. region, age, gender, type of practice and specialty) between respondent and non-respondent physicians.

## Documents

### **Study results**

[Instanyl-5001 Study Report 24 Apr 2016.pdf](#)(3.02 MB)

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## Data management

## Data sources

## **Data sources (types)**

Other

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### **Data sources (types), other**

Prospective patient-based data collection

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

### **CDM mapping**

No

## **Data quality specifications**

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## **Data characterisation**

### **Data characterisation conducted**

Unknown