

# Effectiveness of Xiapex® educational material for healthcare professionals in the treatment of Peyronie's disease - a non-interventional post-authorization safety study (Sobi.Xiapex-PASS01)

**First published:** 20/04/2015

**Last updated:** 31/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS9339

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### Study ID

32787

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### DARWIN EU® study

No

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### Study countries

 Austria

 Czechia

-  Denmark
  -  Finland
  -  Norway
  -  Sweden
  -  United Kingdom
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### **Study description**

This is a non-interventional post-authorization safety study evaluating the effectiveness of the implemented additional risk minimization measure, i.e., the Xiapex educational material for healthcare professionals for treatment of Peyronie's disease. The effectiveness will be assessed through a survey program which includes an Implementation survey and a Follow-up survey.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

Swedish Orphan Biovitrum AB

Multiple centres: 100 centres are involved in the study

## Contact details

### **Study institution contact**

Maria Ilemosoglou [maria.ilemosoglou@sobi.com](mailto:maria.ilemosoglou@sobi.com)

**Study contact**

[maria.ilemosoglou@sobi.com](mailto:maria.ilemosoglou@sobi.com)

### **Primary lead investigator**

Maria Ilemosoglou

**Primary lead investigator**

## Study timelines

### **Date when funding contract was signed**

Planned: 30/01/2015

Actual: 30/01/2015

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### **Study start date**

Planned: 01/09/2016

Actual: 24/04/2015

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### **Data analysis start date**

Planned: 01/05/2017

Actual: 05/03/2018

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

Planned: 31/12/2018

Actual: 21/11/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Swedish orphan Biovitrum AB

## 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:**

Disease /health condition

Human medicinal product

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#### **Study type:**

Non-interventional study

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

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Primary data collection

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**Main study objective:**

The study objective is to evaluate the effectiveness of the Xiapex® educational material as an additional risk minimization measure for healthcare professionals in the treatment of Peyronie’s disease.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Physicians survey, Post-authorization safety study

## Study drug and medical condition

**Medicinal product name**

XIAPEX

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**Medical condition to be studied**

Peyronie's disease

## Population studied

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

Physicians from Austria, Czech Republic, Denmark, Finland, Norway, Sweden, Spain and the United Kingdom registering in the MAH's Peyronie's Trained Physicians database who have completed the Xiapex education material for usage of Xiapex in the treatment of Peyronie's Disease.

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## **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
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## **Estimated number of subjects**

30

# Study design details

## **Data analysis plan**

Categorical data from the Implementation survey and the Follow-up survey will be summarized using frequency counts and percentages using the categories defined in the survey. Adverse events identified will be coded using MedDRA. Number of responders and non-responders will be summarized in total and by country, and also by specialty.

## 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

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### Data sources (types), other

Physician surveys assessing effectiveness of Xiapex education material.

## 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