Survey on the knowledge and use of the Jext prescriber's checklist among physicians – a post-authorisation safety study (XX-JX-01)

First published: 05/04/2019 Last updated: 02/01/2020



**Study status** 

Finalised



### Administrative details

EU PAS number	
EUPAS29289	
Charles ID	
Study ID	
32970	
DARWIN EU® study	
No	
Study countries	
Ireland	

Research institutions and networks

### **Institutions**

### **ALK-Abelló**

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Institution

### Contact details

### **Study institution contact**

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Study contact

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### **Primary lead investigator**

Andreas Slyngborg Holst

**Primary lead investigator** 

# Study timelines

Date when funding contract was signed

Actual: 18/12/2018

Study start date

Planned: 01/06/2019

Actual: 11/04/2019

#### Data analysis start date

Actual: 26/06/2019

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

Planned: 01/12/2019 Actual: 17/09/2019

# Sources of funding

Pharmaceutical company and other private sector

## More details on funding

ALK-Abelló A/S

## Regulatory

Was the study required by a regulatory body?

No

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

#### Study type:

Non-interventional study

#### Scope of the study:

Effectiveness study (incl. comparative)

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

Primary data collection

#### Main study objective:

The Jext prescriber's checklist constitutes a risk minimisation measure (RMM) for Jext, and is included in the Jext risk management plan. As a consequence, effectiveness of the RMM should be evaluated following its implementation into the market. The objective of this study is to assess the effectiveness of the implementation of the Jext prescriber's checklist.

## Study Design

### Non-interventional study design

Other

### Non-interventional study design, other

Post authorization study

## Study drug and medical condition

#### **Anatomical Therapeutic Chemical (ATC) code**

(C01CA24) epinephrine epinephrine

# Population studied

#### Short description of the study population

Physicians who has received Jext prescriber's checklist.

#### 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**

50

# Study design details

#### **Outcomes**

To assess the effectiveness of the implementation of the Jext prescriber's checklist.

#### Data analysis plan

Data analysis stage will consist of preparing the total tally of responses for each question posed. In addition, cross tabulations will be prepared for all survey questions against various sub-groups, e.g. physician types, caseloads and

practice setting. In addition to the responses to the questions of the main questionnaire, the number of respondents who have prescribed Jext, but are not familiar with the prescriber's checklist, will be calculated.

# 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

Data collection from panel of physicians

## Use of a Common Data Model (CDM)

### **CDM** mapping

No

## Data quality specifications

Unknown			
Check completer	ness		
Unknown			

### **Check stability**

**Check conformance** 

Unknown

### **Check logical consistency**

Unknown

# Data characterisation

#### **Data characterisation conducted**

No