

# Post-authorisation Safety Study (PASS): Retrospective Medical Chart Review of Patients with PAH Newly Treated With Either Uptravi® (selexipag) or any Other PAH-specific Therapy (EXTRACT)

**First published:** 06/10/2022

**Last updated:** 15/08/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS49227

---

### Study ID

103768

---

### DARWIN EU® study

No

---

### Study countries

Lithuania

Netherlands

- Slovakia
  - Spain
  - Sweden
  - Switzerland
  - United Kingdom
- 

### Study status

Finalised

## Research institutions and networks

### Institutions

#### Actelion Pharmaceuticals

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

University of Calgary Calgary, Canada, Saint Jopseph Healthcare Hamilton, Canada, Vancouver General Hospital Vancouver, Canada, PAH Center VFN Prague General University Hospital Prague, Czeck Republic, CHU Nice Hopital Pasteur Nice, France, Ospedale San Bortolo Vicenza, Italy,

Vilnius University Hospital - Santaros Klinikos  
Vilnius, Lithuania, Uniwersyteckie Centrum  
Kliniczne Gdansk, Poland, Europejskie Centrum  
Zdrowia Otwock, Poland, Vychodoslovensky ustav  
srdcovych a cievnych chorob (VUSCH) Kosice.  
Slovakia

## Contact details

### Study institution contact

Fabrice Kiefer [fkiefer@its.jnj.com](mailto:fkiefer@its.jnj.com)

Study contact

[fkiefer@its.jnj.com](mailto:fkiefer@its.jnj.com)

### Primary lead investigator

Audrey Muller

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 20/10/2021

Actual: 20/10/2021

---

**Study start date**

Planned: 28/02/2023

Actual: 10/02/2023

---

**Date of final study report**

Planned: 29/03/2024

Actual: 07/03/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Actelion Pharmaceuticals Ltd, a Janssen pharmaceutical company of Johnson and Johnson

## Study protocol

[15Aug2024-REDACTED\\_Protocol-FD-67896049PAH0002-588005\\_1363699.pdf](#)

(1009.78 KB)

## Regulatory

**Was the study required by a regulatory body?**

Yes

---

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

EU RMP category 3 (required)

# Other study registration identification numbers and links

67896049PAH0002

## Methodological aspects

### Study type

#### Study type list

**Study type:**

Non-interventional study

---

**Scope of the study:**

Safety study (incl. comparative)

**Main study objective:**

This retrospective medical chart review study aims to further characterise the safety profile of Uptravi when used in clinical practice, and to describe clinical characteristics and outcomes of patients newly treated with Uptravi or newly treated with any other PAH-specific therapy who were never treated with Uptravi in the international post-marketing setting.

### Study Design

**Non-interventional study design**

Cohort

Other

---

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

Retrospective Medical Chart Review

## Study drug and medical condition

### **Medicinal product name**

UPTRAVI

---

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

Pulmonary arterial hypertension

## Population studied

### **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**

910

## Study design details

## Outcomes

Primary outcome: MACE and all-cause death

Secondary outcomes: important identified or potential risks of Uptravi

---

## Data analysis plan

a) Summary statistics of demographics, disease characteristics and clinical course in Uptravi exposed patients and patients initiating other PAH-specific therapies. b) Occurrence and incidence rate during Uptravi exposure period of all-cause death and the important identified and potential risks of Uptravi, including MACE, in the Uptravi exposed patients. c) Occurrence and incidence rates of MACE and all-cause death in the Uptravi cohort and the Other PAH-specific cohort.

## Documents

### Study results

[15Aug2024-REDACTED\\_Interim CSR #7-Body-67896049PAH0002\\_AC-065A401-1119952\\_1363698.pdf](#) (2.52 MB)

---

## 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**

Retrospective patient chart review

## 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**

No