# A Retrospective Cohort Study for Estimating Incidence Rates of Infusion Site Events for ABBV-951 for the Treatment of Advanced Parkinson's Disease

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# Administrative details

EU PAS number	
EUPAS100000050	
Study ID	
Study ID	
100000050	
DARWIN EU® study	
No	
Study countries	
Finland	
France	

### Study description

The overall aim of this study is to evaluate the effectiveness of additional risk minimization measures (aRMM) by estimating incidence rates of infusion site events (i.e., infusion site infections and/or serious infusion site reactions) in Parkinson disease (PD) patients exposed to ABBV-951 in real-world clinical practice, using data sources from Finland and France. The frequency of infusion site events observed in this real-world study will be interpreted in context of the predefined reference value which is the frequency of the infusion site events reported in the AbbVie clinical trial. The following objectives will be investigated among patients with advanced PD following initiation of treatment with ABBV-951:

- To quantify the incidence rate of first infusion site events (first infusion site infection OR first serious infusion site reactions)
- To quantify the incidence rate of first infusion site infection
- To quantify the incidence rate of first serious infusion site reaction

### **Study status**

Planned

### Research institutions and networks

## Institutions

Global Database Studies, IQVIA
Czechia
Finland
Germany

☐ Slovakia
Spain
First published: 17/01/2011
Last updated: 31/07/2024
Institution Other ENCePP partner

AbbVie

# Contact details

### **Study institution contact**

Mickael Arnaud PAS\_registrations@iqvia.com

Study contact

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### Primary lead investigator

Mickael Arnaud

**Primary lead investigator** 

# Study timelines

Date when funding contract was signed

Planned: 01/11/2022

Actual: 03/11/2022

### Study start date

Planned: 01/09/2026

### Data analysis start date

Planned: 01/03/2028

### Date of final study report

Planned: 31/12/2029

# Sources of funding

Pharmaceutical company and other private sector

# More details on funding

AbbVie Inc.

# Study protocol

P24151-Protocol v1.0 Redacted.pdf (1.24 MB)

# 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)

# Methodological aspects

# Study type

### Study type list

### **Study topic:**

Human medicinal product

### Study type:

Non-interventional study

### **Data collection methods:**

Secondary use of data

### Study design:

A longitudinal, retrospective cohort study of individuals with advanced PD treated with ABBV-951 in Finland and France. The overall study period will be from the date of market availability (anticipated Q4 2023) until Q1 2027. Index date will be defined as the date of first initiation of ABBV-951.

### Main study objective:

- To quantify the incidence rate of first infusion site event (first infusion site infection OR first serious infusion site reaction)
- To quantify the incidence rate of first infusion site infection
- To quantify the incidence rate of first serious infusion site reaction

# Study Design

### Non-interventional study design

Cohort

# Study drug and medical condition

### Name of medicine, other

Foslevodopa/Foscarbidopa

### Medical condition to be studied

Parkinson's disease

# Population studied

### **Special population of interest**

**Immunocompromised** 

Other

### Special population of interest, other

Diabetes Mellitus

# Study design details

### **Outcomes**

- Infusion site event (first occurrence only) defined as infusion site infection OR serious infusion site reaction
- Infusion site infection (first occurrence only)
- Serious infusion site reactions (first occurrence only)

# 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 source(s)

Système National des Données de Santé (French national health system main database)

Longitudinal Patient Data - France

Terveydenhuollon hoitoilmoitusrekisteri (Finland Care Register for Health Care)

### Data source(s), other

PMSI == Programme de Médicalisation des Systèmes d'Information;

AvoHILMO = Register of Primary Health Care Visits;

Finnish EMR:

Prescription Registers Finland.

### Data sources (types)

Administrative healthcare records (e.g., claims)

Drug prescriptions

Electronic healthcare records (EHR)

Pharmacy dispensing records

# Use of a Common Data Model (CDM)

### **CDM** mapping

No

# Data quality specifications

# Unknown Check completeness Unknown

### **Check stability**

**Check conformance** 

Unknown

# **Check logical consistency**

Unknown

# Data characterisation

### **Data characterisation conducted**

Unknown