

# Survey to assess physicians' knowledge of Exjade posology and biological monitoring recommendations as described in the Educational Materials

**First published:** 27/10/2023

**Last updated:** 13/02/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS104950

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### Study ID

104951


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### DARWIN EU® study

No

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### Study countries

 Austria

 Belgium

 France

-  Germany
  -  Hungary
  -  Italy
  -  Poland
  -  Spain
  -  Sweden
  -  United Kingdom
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## Study description

The main objective of this survey is to assess whether sufficient levels of knowledge of posology and biological monitoring recommendations as described in the Exjade EU Summary of Product Characteristics (SmPC) can be attained among prescribers of Exjade/deferasirox, through the provision of Exjade EMs (which includes a Physician's reference checklist) developed by Novartis.

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## Study status

Finalised

# Research institutions and networks

## Institutions

### Novartis Pharmaceuticals

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

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

Institution

## Contact details

### Study institution contact

Novartis Clinical Disclosure Officer

[Trialandresults.registries@novartis.com](mailto:Trialandresults.registries@novartis.com)

Study contact

[Trialandresults.registries@novartis.com](mailto:Trialandresults.registries@novartis.com)

### Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 23/08/2022

Actual: 23/08/2022

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### Study start date

Planned: 31/01/2024

Actual: 12/01/2024

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### Data analysis start date

Planned: 15/02/2024

Actual: 15/02/2024

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### Date of final study report

Planned: 20/12/2024

Actual: 10/09/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Novartis AG

## Study protocol

[CICL670A2429 protocol V01 clean\\_Redacted.pdf](#) (651.25 KB)

## 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)

## Other study registration identification numbers and links

CICL670A2429

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Main study objective:**

To evaluate the effectiveness of Educational Material for Exjade (deferasirox)

## Study drug and medical condition

**Medicinal product name**

EXJADE

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**Study drug International non-proprietary name (INN) or common name**

DEFERASIROX

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**Anatomical Therapeutic Chemical (ATC) code**

(V03AC03) deferasirox

deferasirox

## 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)
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**Estimated number of subjects**

## Study design details

### Outcomes

Percentage of correct response rate to the physician survey questionnaire

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### Data analysis plan

Physician knowledge will be evaluated in each of the two key sections separately: posology of Exjade, and biological monitoring recommendation for Exjade.

Success criteria of the survey will be based on the observed mean correct response rate for each section.

A threshold of correct response rate of at least 70% or more will be considered as a success for each section of the survey.

The mean correct response rate (in percentage) for each survey section is calculated taking the average of the proportion of correct responses within each section (total number of correct responses X 100/total number of questions in each section) based on all physicians participating in the survey.

## Documents

### Study report

[CICL670A2429 icl670--physician-survey-report\\_Redacted.pdf](#) (5.33 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

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### Data sources (types), other

Survey

## 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**

No