

# A Post-Authorization Safety Study to Evaluate the Safety of Abrocitinib Exposure During Pregnancy in United States Healthcare Databases

**First published:** 04/04/2024

**Last updated:** 19/04/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000096

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### Study ID

1000000096

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study description

This US population-based, non-interventional, cohort study will evaluate the risk of adverse pregnancy and infant outcomes among women with moderate-to-severe AD who are exposed to abrocitinib during pregnancy compared to those unexposed during pregnancy. Pregnancies with start dates occurring during the period 14 January 2022 to Q4 2025, and infants born to the women, will be included. The main outcome of interest will be MCMs. Additional outcomes of interest include other adverse infant outcomes (preterm birth, SGA) and pregnancy outcomes (stillbirth, spontaneous abortion).

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### Study status

Ongoing

## Research institutions and networks

### Institutions

[Pfizer](#)

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

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

Institution

[Harvard Pilgrim Health Care Institute](#)

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

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

Institution

## Contact details

### Study institution contact

Jenny Sun jenny.sun@pfizer.com

Study contact

[jenny.sun@pfizer.com](mailto:jenny.sun@pfizer.com)

### Primary lead investigator

Jenny Sun

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 07/09/2022

Actual: 07/09/2022

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### Study start date

Planned: 31/12/2022

Actual: 31/12/2022

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### Data analysis start date

Planned: 01/03/2024

Actual: 17/04/2024

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### Date of final study report

Planned: 30/06/2028

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

[B7451098\\_ABROCITINIB UPDATED PROTOCOL\\_18NOV2022\\_Redacted.pdf](#) (2.88 MB)

## Regulatory

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

Yes

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

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Study design:**

This US population-based, non-interventional, cohort study will evaluate the risk of adverse pregnancy and infant outcomes among women with moderate-to-severe AD who are exposed to abrocitinib during pregnancy compared to those unexposed during pregnancy.

**Main study objective:**

To describe and compare the adverse pregnancy and infant outcomes among women with moderate-to-severe AD who are exposed to abrocitinib during pregnancy and women with moderate-to-severe AD who are not exposed to abrocitinib.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

CIBINQO

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

ABROCITINIB

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

(D11AH08) abrocitinib

abrocitinib

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### **Additional medical condition(s)**

Moderate-to-severe atopic dermatitis (AD)

## Population studied

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

The study population will include singleton pregnancies among women 12 to 49 years of age diagnosed with moderate-to-severe AD who are members of participating Sentinel Data Partners (DPs).

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### **Age groups**

- Adolescents (12 to < 18 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
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### **Special population of interest**

Pregnant women

## Study design details

### **Setting**

The study will be conducted using data provided by US Data Partners in the FDA's Sentinel System. The study population will include singleton pregnancies among women 12 to 49 years of age diagnosed with moderate-to-severe AD who are members of participating Sentinel Data Partners (DPs).

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### **Outcomes**

The main outcome of interest will be MCMs. Additional outcomes of interest include other adverse infant outcomes (preterm birth, SGA) and pregnancy outcomes (stillbirth, spontaneous abortion).

## 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), other**

Sentinel Data Partners

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### **Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

## Use of a Common Data Model (CDM)

## **CDM mapping**

Yes

## **CDM Mappings**

### **CDM name**

Sentinel

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### **CDM website**

<https://www.sentinelinitiative.org/methods-Data-tools/sentinel-common-Data-model>

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## 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