# Prospective, Registry-Based Observational Cohort Study of Ritlecitinib Safety in Pregnancy

First published: 10/09/2024

**Last updated:** 19/06/2025





# Administrative details

**Study description** 

EU PAS number	
EUPAS1000000296	
Charles ID	
Study ID	
100000296	
DARWIN EU® study	
-	
No	
Study countries	
United States	
United States	

Research question: Is there an increased risk of adverse maternal and/or infant outcomes in individuals with AA exposed to ritlecitinib during pregnancy? Primary objective: To estimate the prevalence of major congenital malformation [MCM] births (primary outcome) among pregnant individuals with alopecia areata [AA] who are (1) exposed to ritlecitinib (exposed cohort) and (2) unexposed to ritlecitinib (comparator cohort).

Secondary objectives: 1. To estimate the prevalence of the following secondary outcomes in the 2 cohorts: SAB, elective termination, pregnancy complications (pre-eclampsia, eclampsia), stillbirth, preterm birth, SGA, minor congenital malformation, infant postnatal growth deficiency, and infant developmental delay. 2. To estimate the RR of each of the study outcomes in the exposed versus unexposed cohorts, if sample size permits.

Study design: This registry-based, prospective observational cohort study will enroll and follow pregnant individuals in the US, including individuals with AA exposed to ritlecitinib during pregnancy and individuals with AA unexposed to ritlecitinib during pregnancy. This study will be a new, product-based pregnancy registry. Participation in the registry is voluntary and participants can withdraw their consent to participate at any time. Data will be collected from enrolled pregnant individuals and the HCPs involved in their care or the care of their infants.

The primary study outcome is MCM and the secondary outcomes are SAB, elective termination, pregnancy complications (pre-eclampsia, eclampsia), stillbirth, preterm birth, SGA, minor congenital malformation, postnatal growth deficiency, and infant developmental delay. The main measures of effect are the prevalence of each outcome in the 2 study cohorts and, if sample size permits, the RR of each outcome, comparing the cohorts.

#### **Study status**

Planned

## Research institutions and networks

## **Institutions**

## Pfizer

First published: 01/02/2024

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

Institution

# Pharmaceutical Product Development (PPD)

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

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

Institution

# Contact details

### **Study institution contact**

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Study contact

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## **Primary lead investigator**

Monica Bertoia

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Planned: 10/06/2024 Actual: 10/06/2024

#### Study start date

Planned: 31/10/2024

#### Data analysis start date

Planned: 28/02/2029

#### Date of interim report, if expected

Planned: 28/02/2030

#### Date of final study report

Planned: 30/06/2035

# Sources of funding

• Pharmaceutical company and other private sector

## More details on funding

Pfizer 100%

# Study protocol

B7981095\_RITLECITINIB PREGNANCY REGISTRY PROTOCOL\_V2.0\_15JUN2024 clean.pdf (813.28 KB)

# B7981095\_RITLECITINIB PREGNANCY REGISTRY PROTOCOL V3.0 12FEB2025.pdf (867.21 KB)

# Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

# Other study registration identification numbers and links

B7981095

# Methodological aspects

Study type

Study type list

**Study topic:** 

Human medicinal product

Study type:

Non-interventional study

#### Scope of the study:

Safety study (incl. comparative)

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

Primary data collection

#### Study design:

This study is a prospective, registry-based observational cohort study. This study will be a new, product-based pregnancy registry. Data will be collected from eligible participants in the US.

#### Main study objective:

Primary objective: To estimate the prevalence of MCM births among pregnant individuals with AA who are (1) exposed to ritlecitnib and (2) unexposed to ritlecitnib.

# Study Design

#### Non-interventional study design

Cohort

# Study drug and medical condition

#### Name of medicine

**LITFULO** 

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

**RITLECITINIB** 

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

(L04AF08) ritlecitinib

#### Medical condition to be studied

Pregnancy

Alopecia areata

# Population studied

#### Short description of the study population

Two cohorts of pregnant individuals with AA in the US. The study cohorts will include individuals exposed to ritlecitinib during pregnancy and individuals unexposed to ritlecitinib during pregnancy who are enrolled in the registry.

#### Age groups

ΑII

Paediatric Population (< 18 years)

Preterm newborn infants (0 - 27 days)

Term newborn infants (0 - 27 days)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

#### Special population of interest

Pregnant women

#### **Estimated number of subjects**

400

# Study design details

#### Setting

The study population will be derived from eligible individuals in the US enrolled in the pregnancy registry.

#### **Outcomes**

Outcomes of interest

Primary: Major congenital malformation (MCM)

Secondary: Spontaneous abortion (SAB), elective termination, pregnancy complications (pre-eclampsia, eclampsia), stillbirth, preterm birth, SGA, minor congenital malformation, infant postnatal growth deficiency, and infant developmental delay.

#### Data analysis plan

The analysis population will include valid participants who were prospectively enrolled in the registry, are not exposed to teratogens or investigational medications during pregnancy, and who are not considered lost to follow up. Patient characteristics will be summarized with descriptive statistics for each cohort. The number of observations, median, mean, standard deviation, minimum, and maximum will be reported for each continuous variable. The frequency and percentage per category will be reported for each categorical

variable. Prevalence of the outcomes of interest will be calculated according to the conventions described in the protocol. In general, the prevalence of each outcome will be calculated by dividing the number of cases of the outcome by the appropriate denominator for that particular outcome, based on clinical knowledge. For most outcomes, the analysis population (denominator) will be the number of pregnant individuals with pregnancy outcome data, the number of live births, or the number of infants with follow-up data at the timepoint of interest, as appropriate; however, for some outcomes, the analysis population (denominator) will be restricted based on certain relevant factors. Comparative analyses will be conducted for each outcome if sample size permits. Crude (unadjusted) RRs (and corresponding 95% CIs) will be calculated using Exact methods. Adjusted RRs will be calculated using generalized linear models (binomial family) with a log (RR) link and weighted by IPTW. The Clopper-Pearson method will be used to derive 95% Cls. IPTW will be calculated using propensity scores estimated from propensity score models. Each individual's propensity score will be estimated using a logistic regression model with exposure status as the outcome (dependent variable). Detailed methodology for summary and statistical analysis of the data collected in this study will be documented in a statistical analysis plan

# 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

This will be a new, product-based pregnancy registry conducted by PPD (part of Thermo Fisher Scientific).

#### Data sources (types)

Other

#### Data sources (types), other

Primary data collection

## 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**

Unknown