Pregnancy Exposures and Outcomes in Women with Inflammatory Bowel Disease Treated with Risankizumab: A Cohort Study Utilizing Large Electronic Healthcare Databases with Mother-Baby Linkage in the United States

First published: 06/08/2024

Last updated: 18/08/2025





### Administrative details

#### **EU PAS number**

EUPAS1000000283

### Study ID

1000000283

### **DARWIN EU® study**

No

#### **Study countries**

	United	States
--	--------	--------

### **Study status**

Ongoing

### Contact details

### **Study institution contact**

Clinical Trial Disclosures CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

### **Primary lead investigator**

Susan Andrade

**Primary lead investigator** 

# Study timelines

### Date when funding contract was signed

Planned: 12/07/2022

### Study start date

Actual: 07/04/2025

### Data analysis start date

Actual: 07/04/2025

### **Date of final study report**

Planned: 30/06/2033

# Sources of funding

• Pharmaceutical company and other private sector

### More details on funding

AbbVie

### Study protocol

P23-653\_Protocol v2.0\_Abstract\_Redacted.pdf (102.6 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

P23-653

# Methodological aspects

Study type

Study type list

#### **Study topic:**

Disease /health condition

#### Study topic, other:

Inflammatory Bowel Disease

#### **Study type:**

Non-interventional study

#### Scope of the study:

Safety study (incl. comparative)

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

Secondary use of data

### Study design:

The study will be a population-based, non-interventional, cohort study of pregnant women with moderate-to-severe Inflammatory Bowel Disease (IBD). The primary comparison will be among women with moderate-to-severe IBD exposed to risankizumab versus those exposed to the comparator treatment group.

### Main study objective:

The study aim is to evaluate the safety of risankizumab during pregnancy in women with moderate-to-severe IBD. The outcomes of this cohort study are major congenital malformations (MCMs) of the infant among live birth pregnancies, Pregnancy outcomes: live birth, spontaneous abortion, elective abortion, stillbirth and Infant outcomes: premature birth, small for gestational age (SGA), neonatal deaths, serious infections.

## Study Design

### Non-interventional study design

Cohort

### Study drug and medical condition

#### **Medicinal product name**

**SKYRIZI** 

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

**RISANKIZUMAB** 

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

(L04AC18) risankizumab

risankizumab

#### Medical condition to be studied

Inflammatory bowel disease

### Population studied

#### Age groups

- Adolescents (12 to < 18 years)</li>
- Adults (18 to < 65 years)

### **Special population of interest**

Pregnant women

### **Estimated number of subjects**

600

# Study design details

### Data analysis plan

The prevalence (%) of the main outcome (MCMs) and additional outcomes, including other adverse infant outcomes and pregnancy outcomes (live birth, spontaneous abortion, elective abortion, stillbirth), and their 95% confidence intervals (CIs) will be calculated among eligible risankizumab-exposed pregnancies and the corresponding matched comparator biologic-exposed pregnancies.

### 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.

### Use of a Common Data Model (CDM)

### **CDM** mapping

No

## Data quality specifications

#### **Check conformance**

Yes

### **Check completeness**

Yes

### **Check stability**

Yes

### **Check logical consistency**

Yes

# Data characterisation

### **Data characterisation conducted**

No