Post-Authorization Safety Study to Monitor Pregnancy and Infant Outcomes Following Administration of Dupilumab During Planned or Unexpected Pregnancy in North America

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# Administrative details

<b>EU PAS number</b>		
EUPAS43819		
Study ID		
43820		
DARWIN EU® study		
No		
Study countries		
Canada		
United States		

#### Study description

The objective is to evaluate the potential effect of exposure to dupilumab in pregnancy compared to the primary comparison group of disease-matched pregnant women who are not exposed to dupilumab, and the secondary comparison group of healthy pregnant women. The primary outcome of the study is major structural defects, and the secondary outcomes of the study are spontaneous abortion/miscarriage, stillbirth, elective termination/abortion, premature delivery, small for gestational age, pattern of 3 or more minor structural defects, postnatal growth of live born children to 1 year of age, postnatal serious or opportunistic infections in live born children to 1 year of age, and hospitalizations in live children up to 1 year of age.

#### **Study status**

Ongoing

### Research institutions and networks

### Institutions

### Regeneron Pharmaceuticals

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Institution

### **Networks**

European Forum for Primary Care (EPFC)
Austria
Belgium
Bulgaria
Croatia
Cyprus
Czechia
☐ Denmark
Estonia
European Union
Finland
France
Germany
Greece
Hungary
Iceland
Ireland
Italy
Latvia
Liechtenstein
Lithuania
Luxembourg
Malta Malta
☐ Netherlands
Norway
Poland
Portugal
Romania

☐ Slovakia
☐ Slovenia
☐ Spain
Sweden
Switzerland
United Kingdom (Northern Ireland)
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Network ENCePP partner

# Organization of Teratology Information Specialists (OTIS) Network

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Network

### Contact details

### Study institution contact

Study Director Regeneron clinicaltrialdisclosureteam@regeneron.com

Study contact

clinicaltrialdisclosureteam@regeneron.com

### **Primary lead investigator**

# Study Director Regeneron

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Actual: 11/01/2018

#### Study start date

Actual: 24/10/2018

#### Data analysis start date

Planned: 09/01/2026

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

Planned: 09/07/2026

# Sources of funding

- Other
- Pharmaceutical company and other private sector

## More details on funding

Regeneron, Sanofi

# 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

R668-AD-1639,NCT04173442

# Methodological aspects

## Study type

## Study type list

### Study type:

Non-interventional study

#### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

#### Main study objective:

The objective is to evaluate the potential effect of exposure to dupilumab in pregnancy compared to the primary comparison group of disease-matched pregnant women who are not exposed to dupilumab, and the secondary comparison group of healthy pregnant women.

# Study Design

#### Non-interventional study design

Cohort

# Study drug and medical condition

#### Medical condition to be studied

Dermatitis atopic

**Asthma** 

# 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)

### Special population of interest

Pregnant women

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

500

# Study design details

#### **Outcomes**

Rate of major structural defects, • Incidence of spontaneous abortion or miscarriage and stillbirth • Incidence of elective termination/abortion • Incidence of premature delivery • Incidence of small for gestational age • Incidence of a pattern of 3 or more minor structural defects • Postnatal growth deficiency • Incidence of postnatal serious or opportunistic infections and hosptializations in live born children

#### Data analysis plan

The analyses in this study aim to characterize and quantify outcomes of interest. Following descriptive analyses of the study groups, frequencies of outcomes by group and adjusted risk ratios will be calculated to compare dupilumab exposed groups to the non-exposed groups.

### 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

### Data sources (types), other

Exposure registry

### 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**

No