# A Retrospective Cohort Study Using Health Administrative Claims Databases to Assess Adverse Pregnancy and Infant Outcomes in Women with Psoriasis Who Were Exposed to Guselkumab Versus Other Biologic Therapies During Pregnancy. PASS-EMA

**First published:** 08/08/2019

**Last updated:** 12/01/2026

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS30740

**Study ID**

103402

**DARWIN EU® study**

No

**Study countries**

United States

**Study description**

TREMFYA (guselkumab) pregnancy healthcare database study. PASS-EMA

**Study status**

Ongoing

## Contact details

**Study institution contact**

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**Study contact**

RA-RNDUS-ClinclTrlsEU@its.jnj.com

**Primary lead investigator**

Kevin Haynes

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Actual: 13/07/2017

**Study start date**

Actual: 01/09/2025

**Data analysis start date**

Planned: 31/12/2022

Actual: 01/02/2023

**Date of final study report**
Planned: 30/12/2030

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Janssen R&D

## 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)

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

To estimate and compare the prevalence of MCM between infants born to women with PsO who were exposed to guselkumab and infants born to women with PsO who were exposed to other biologics during pregnancy, To estimate and compare the risk of a composite adverse pregnancy outcome between women with PsO exposed to guselkumab and women with PsO exposed to other biologics during pregnancy

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

This is a phase 4, observational, retrospective cohort study using electronic health administrative claims databases in the US

## Study drug and medical condition

**Medicinal product name**

TREMFYA

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**Medical condition to be studied**

Psoriasis

# Population studied

**Age groups**

- Adults (18 to < 46 years)

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**Estimated number of subjects**

100

# Study design details

**Outcomes**

Major congenital malformation AND composite adverse outcome of major congenital malformation, spontaneous abortion, stillbirth, small for gestational age, preterm birth, neonatal death combined, Spontaneous abortion, stillbirth, preterm birth, small for gestational age, neonatal death, and infant infections

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**Data analysis plan**

Descriptive analysis will include maternal characteristics and pregnancy outcomes according to PsO treatment during pregnancy, including guselkumab, other biologics, non-biologics, photo-therapies, or topical alone. The prevalence of the adverse pregnancy outcomes will be estimated as the number of pregnancies ending with these outcomes divided by the number of completed pregnancies at-risk during the study period. A 1:5 matched sample will be constructed based on propensity score (PS) for pregnancy exposure to guselkumab versus other biologics to balance the distribution of potential confounders. The primary analysis will use logistic regression model to estimate

the risk ratio of the adverse pregnancy outcomes associated with maternal exposure to guselkumab during the pre-specified at-risk time windows. For the infant outcome of hospitalized infections up to 1 year of age, a Cox regression model will be conducted.

# 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)**

Administrative healthcare records (e.g., claims)

## Use of a Common Data Model (CDM)

**CDM mapping**

Yes

**CDM Mappings**

**CDM name**

OMOP

**CDM website**

https://www.ohdsi.org/Data-standardization/

## Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No