# A Non-Interventional Multi-Database Post-Authorisation Study to Assess PregnancyRelated Safety Data from Women with SLE Exposed to Anifrolumab (ROSE PASS)

**First published:** 16/01/2024

**Last updated:** 20/10/2026

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS108728

**Study ID**

199011

**DARWIN EU® study**

No

**Study countries**

Denmark

Finland

France

Germany

United States

**Study description**

The aim of this study is to describe congenital malformations, adverse pregnancy and birth outcomes in pregnancies/offspring from women with moderate/severe SLE exposed to anifrolumab during pregnancy and to compare with outcomes in women with moderate/severe SLE who are exposed to other SOC but not anifrolumab. Adverse outcomes related to infant growth up to one year of age will also be investigated.

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### IQVIA

United Kingdom

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**Institution** **Non-Pharmaceutical company** **ENCePP partner**

# Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Ana Cristina Santos

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 15/03/2022

Actual: 15/03/2022

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**Study start date**

Planned: 05/01/2026

Actual: 21/05/2026

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**Date of final study report**

Planned: 31/03/2032

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

AstraZeneca

## Study protocol

AZ SLE anifrolumab pregnancy PASS_Protocol v3.0_28Aug2023_redacted.pdf (2.4 MB)

AZSLEA~2.PDF (2.59 MB)

## 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 topic:**

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**Study design:**

The study will utilise a non-interventional longitudinal population-based retrospective cohort design. It will be conducted using secondary data derived from multiple databases which record longitudinal medical data.

**Main study objective:**

The aim of this study is to describe major congenital malformations (MCM), adverse pregnancy, and birth outcomes in pregnancies/offspring from women with moderate/severe SLE exposed to anifrolumab and compare the occurrence of these outcomes to outcomes observed in women with moderate/severe SLE whose pregnancies were not exposed to anifrolumab

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name, other**

anifrolumab

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

ANIFROLUMAB

**Anatomical Therapeutic Chemical (ATC) code**

(L04AG11) anifrolumab

anifrolumab

**Medical condition to be studied**

Systemic lupus erythematosus

# Population studied

**Short description of the study population**

For MCM analysis, a total number of 732 live and non-live births (183 anifrolumab and 549 comparator) using a matching ratio of 1:3.
For the select adverse pregnancy loss outcomes analysis, a total number of 244 pregnancies (61 anifrolumab and 183 comparator) using a matching ratio of 1:3 would be necessary.

**Age groups**

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

**Special population of interest**

Pregnant women

**Estimated number of subjects**

976

# Study design details

**Outcomes**

The primary outcomes of interest are MCM (defined as a composite of all major MCMs) occurring in live or non-live offspring and select pregnancy loss outcomes (composite of spontaneous abortion and stillbirth), Minor congenital malformations (mCM), Adverse pregnancy outcomes, Adverse birth outcomes

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**Data analysis plan**

A full description of the analytical approach will be developed and described in the SAP. Also details on data derivations, category definitions, analyses, and presentation of the study results will be provided in SAP.

The SAP will be finalised prior to the conduct of the study analyses.

All study results will be presented separately for each data source in the study reports, as appropriate when data become available.

The full study reports for all data sources, including all descriptive, comparative, exploratory, and sensitivity analyses, as well as the meta-analysis results will be provided in the final report.

# 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)**

Danish registries (access/analysis)

**Data source(s), other**

National Health Data System - SNDS, Rheuma-Kindwunsch und Schwangerschaft - RHEKISS, HealthCore Integrated Research Database - HIRD United States, Finnish Registries, HV MOM-US

**Data sources (types)**

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Other

**Data sources (types), other**

Pharmacy dispensing records, Hospital medication registries

## 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