

# Meta-Analysis Plan for Study Number 201182, GSK1550188, SLE, Pregnancy Analysis

**First published:** 26/10/2015

**Last updated:** 03/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS11405

---

### Study ID

50499


---

### DARWIN EU® study

No

---

### Study countries

 United Kingdom

 United States

---

### Study description

The purpose of the study is to evaluate maternal, fetal and infant outcome data for subjects with systemic lupus erythematosus (SLE) who were exposed to belimumab during pregnancy. This is an aggregate analysis of pregnancy outcomes and relevant clinical data from the belimumab clinical trials pulling together data from the clinical trial and safety databases up to 08 March 2014.

---

## Study status

Finalised

## Research institutions and networks

### Institutions

#### GlaxoSmithKline (GSK)

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

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

Institution

## Contact details

### Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure  
Advisor Pharma.CDR@gsk.com

Study contact

[Pharma.CDR@gsk.com](mailto:Pharma.CDR@gsk.com)

### Primary lead investigator

# GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 15/12/2014

Actual: 15/12/2014

---

### **Study start date**

Planned: 15/05/2015

Actual: 29/01/2015

---

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

Planned: 15/11/2015

Actual: 19/11/2015

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

## Study protocol

[gsk-201182-reporting-and-analysis-plan-redact.pdf](#) (610.07 KB)

## Regulatory

## Was the study required by a regulatory body?

No

---

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

#### Study topic:

Disease /health condition

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

---

#### Main study objective:

To evaluate maternal, fetal and infant outcome data for subjects with systemic lupus erythematosus (SLE) who were exposed to belimumab during pregnancy.

## Study Design

## **Non-interventional study design**

Systematic review and meta-analysis

# Study drug and medical condition

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

BELIMUMAB

---

## **Additional medical condition(s)**

SLE and pregnancy

# Population studied

## **Short description of the study population**

Adults subjects diagnosed with systemic lupus erythematosus (SLE) who become pregnant while exposed to belimumab during phase 2-4 clinical trials.

Inclusion criteria:

- All cases involving a pregnant patients are included.

Exclusion criteria:

- Cases involving females over 60 years of age and adult males (where the case was not reported as a partner pregnancy) has been excluded.

---

## **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
- 

## **Special population of interest**

Immunocompromised

Other

Pregnant women

---

### **Special population of interest, other**

Patients with systemic lupus erythematosus

---

### **Estimated number of subjects**

85

## Study design details

### **Outcomes**

The primary objective is to determine if there is an increase in birth defects in infants born to women with SLE who were exposed to belimumab during pregnancy. Secondary outcomes include adverse maternal and infant outcomes, e.g. spontaneous miscarriage, preterm birth and still birth.

---

### **Data analysis plan**

All data will be summarized using descriptive statistics. Continuous variables will be summarized by number of participants, mean, standard deviation, median, lower quartile, upper quartile, minimum and maximum unless otherwise stated. Categorical variables will be summarized by number and percentage in each category. Missing data will be displayed as a separate category where appropriate. The denominator for all percentages will reflect the number of participants within the cohort, unless otherwise stated (e.g. excluding lost to follow-up (LTF)). For primary endpoint birth defects and secondary endpoints (pregnancy outcomes: live birth, neonatal death, stillbirth, spontaneous miscarriage, elective termination, ectopic pregnancy, and molar pregnancy) prevalence rates and 95% confidence intervals will be summarized.

## Documents

## Study results

[gsk-201182-clinical-study-report-redact.pdf](#) (1.29 MB)

---

## Study publications

[Petri M, Landy H, Clowse ME, Gemzoe K, Khamashta M, Kurtinecz M, Levy RA, Liu A...](#)

---

## 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

Prospective patient-based 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**

No