

# SABLE: A 5-Year Prospective Observational Registry to Assess Adverse Events of Interest and Effectiveness in Adults with Active, Autoantibody-Positive Systemic Lupus Erythematosus Treated With or Without Benlysta (Belimumab) (116543)

**First published:** 16/10/2013

**Last updated:** 10/02/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS4966

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### Study ID

45713

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### DARWIN EU® study

No

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## Study countries

- ☐ Argentina
  - ☐ Austria
  - ☐ Belgium
  - ☐ Canada
  - ☐ France
  - ☐ Germany
  - ☐ Israel
  - ☐ Italy
  - ☐ Portugal
  - ☐ Slovakia
  - ☐ Spain
  - ☐ Sweden
  - ☐ United States
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## Study status

Ongoing

# Research institutions and networks

## Institutions

### Quintiles

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

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

Institution

## Contact details

**Study institution contact**

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Study contact

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

**Primary lead investigator**

GSK Clinical Disclosure Advisor

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 31/10/2012

Actual: 31/10/2012

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**Study start date**

Planned: 21/02/2013

Actual: 21/02/2013

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**Date of final study report**

Planned: 18/07/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

## Study protocol

[BEL116543 \(hgs1006-c1124-01\).pdf](#)(358.26 KB)

[gsk-116543-protocol-amend4-redact.pdf](#)(987.99 KB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Main study objective:**

Evaluate the incidence of following AESI over 5 years in adults with active auto antibody positive SLE treated with/without BENLYSTA: Malignancies, Mortality, Opportunistic infections & other infections of interest, Non-melanoma skin cancer, Selected serious psychiatric event, Serious infections.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Multi-center, prospectiv, observational cohort study

## Study drug and medical condition

**Name of medicine**

BENLYSTA

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

BELIMUMAB

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**Medical condition to be studied**

Systemic lupus erythematosus

## 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)

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**Estimated number of subjects**

3000

## Study design details

**Outcomes**

Incidence of the following adverse events of special interest (AESI):

- Malignancies (excluding non-melanoma skin cancers)
- Mortality
- Opportunistic infections and other infections of interest (Appendix 1)
- Non-melanoma skin cancers (NMSC)
- Selected serious psychiatric events (Appendix 2)
- Serious infections

Evaluate the effectiveness measures in adults with active autoantibody-positive SLE treated with/without BENLYSTA:

- Organ damage assessed by SLICC/ACR Damage Index
- Concomitant SLE meds including steroids
- Hospitalization
- Quality of life assessed by SF-12v2 Health Survey
- Fatigue assessed by FACIT-Fatigue Scale

- SLE disease activity assessed by SLEDAI 2000
  - Severe Flare derived by SLE Flare Index
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### **Data analysis plan**

Estimate AESI via incidence rates & compared between cohorts using binomial regression and/or Cox models / Kaplan-Meier plots based on one or more exposure strategies as described:

- (1, 2) patients contribute data until their first treatment switch, or a pre-specified landmark timepoint,
- (3) Ever-taken Benlysta strategy, an event will be attributed to BENLYSTA if the patient was ever exposed to BENLYSTA prior to the event, & to non-Benlysta otherwise,
- (4) patient profile approach, patients are characterized by the switch patterns,
- (5) the as-exposed analysis or marginal structural methods may be used to model treatment switch and explore the long-term treatment effect. Safety analysis may employ a lagged risk window since an AE may be attributed to a treatment after discontinuation. Similar methods will be applied to the effectiveness endpoints. Propensity score methods and/or multivariate regression methods will be used to adjust for potential confounding factors & selection bias.

## **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

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## **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

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## **Check completeness**

Unknown

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## **Check stability**

Unknown

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## **Check logical consistency**

Unknown

# Data characterisation

## **Data characterisation conducted**

No