# 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:** 09/03/2026

Study Finalised

## Administrative details

**EU PAS number**

EUPAS4966

**Study ID**

45713

**DARWIN EU® study**

No

**Study countries**

- Argentina
- Austria
- Belgium
- Canada
- France
- Germany
- Israel
- Italy
- Portugal
- Slovakia
- Spain
- Sweden
- United States

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Quintiles

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

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

**Institution**

# Contact details

**Study institution contact**

GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

**Study contact**

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**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: 08/09/2025

Actual: 05/09/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

## 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

**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 topic:**

Disease /health condition

Human medicinal product

**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Study design:**

This was a multi-center, prospective, observational cohort study.

**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**

Cohort

Other

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**Non-interventional study design, other**

Multi-center, prospective, observational cohort study

## Study drug and medical condition

**Medicinal product name**

BENLYSTA

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

BELIMUMAB

**Anatomical Therapeutic Chemical (ATC) code**

(L04AG04) belimumab

belimumab

**Medical condition to be studied**

Systemic lupus erythematosus

# Population studied

**Short description of the study population**

Adults with active autoantibody-positive systemic lupus erythematosus (SLE) who are treated with or without Benlysta.

**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)

**Estimated number of subjects**

3000

# Study design details

**Setting**

The first participant was enrolled in the study on 21 February 2013 and the last participant last visit was on 28 February 2025. Participants were enrolled at sites in Argentina, Austria, Belgium, Canada, France, Germany, Israel, Italy, Portugal, Slovakia, Spain, Sweden, and the US.

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**Comparators**

Not receiving Benlysta (comparison Non-Benlysta exposure group)

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**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.

## Documents

**Study report**

Clinical Study Report Body Consolidated Anonymised 19 Feb 2026.pdf (8.08 MB)

# 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)**

Other data source

**Data source(s), other**

Prospective patient-based data collection

**Data sources (types)**

Electronic healthcare records (EHR)

## 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