

# DARWIN EU® Treatment patterns of drugs used in adult and paediatric population with systemic lupus erythematosus

**First published:** 06/09/2023

**Last updated:** 30/01/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS106436

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### Study ID

106437

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### DARWIN EU® study

Yes

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### Study countries

 France

 Germany

 Spain

 United Kingdom

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## Study description

Systemic SLE erythematosus: SLE is a multisystem autoimmune disorder of connective tissue characterized by autoantibodies that target nuclear antigens, remissions and flares, and a highly variable clinical presentation, disease course, and prognosis. The disease course is more severe in childhood-onset compared to adult-onset SLE, with higher prevalence of morbidity and lower survival rates. In contrast to adult SLE, there is limited good quality evidence on the treatment of childhood SLE. Therefore, to review new drug applications, it would be important for the European Medicines Agency EMA to understand the current clinical practice of treating SLE in paediatric population and differences with the treatment in adult population. The overall objective of this study is to characterise paediatric and adult patients with SLE diagnosed in the period 2013-2022. This will be a patient-level characterisation and drug utilisation study.

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### [IQVIA NL, Real-World-Evidence](#)

 Netherlands

**First published:** 25/11/2022

**Last updated:** 21/03/2025

**Institution**

Other

ENCePP partner

## Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

 Spain

**First published:** 05/10/2012

**Last updated:** 23/05/2025

**Institution**

Educational Institution

Laboratory/Research/Testing facility

Not-for-profit

ENCePP partner

## Parc de Salut Mar Barcelona (PSMAR)

 Spain

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

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

**Institution**

Hospital/Clinic/Other health care facility

## Bordeaux University Hospital (CHU de Bordeaux)

 France


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

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

**Institution**

Hospital/Clinic/Other health care facility

# Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford

 United Kingdom

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

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


**Institution**

Educational Institution


Hospital/Clinic/Other health care facility


## Networks


### Data Analysis and Real World Interrogation Network (DARWIN EU®)


 Belgium


 Croatia


 Denmark


 Estonia

 Finland


 France


 Germany


 Greece


 Hungary


 Italy


 Netherlands

 Norway

 Portugal

 Spain

 Sweden

 United Kingdom

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

**Last updated:** 30/04/2025

Network

## Contact details

### Study institution contact

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Study contact

[study@darwin-eu.org](mailto:study@darwin-eu.org)

### Primary lead investigator

Daniel Prieto Alhambra

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 06/07/2023

Actual: 06/07/2023

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### Study start date

Planned: 01/01/2013

Actual: 01/01/2013

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

Planned: 31/10/2023

Actual: 01/12/2023

## Sources of funding

- EMA

## Study protocol

[Study Protocol P2 C1-006 Version 2.1 final.pdf](#) (1.93 MB)

## Regulatory

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

Yes

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Drug utilisation

**Study design:**

A retrospective cohort study of all patients newly diagnosed with SLE will be conducted. For the description of each treatment objective, a new drug user cohort will be used to characterise patient-level SLE drug utilisation.

**Main study objective:**

To characterise paediatric and adult patients with SLE.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name, other**

- Cyclosporine
- Fluocortolone
- Paramethasone
- Prednisone
- Triamcinolone
- Cortisone

- Prednylidene
  - Rimexolone
  - Deflazacort
  - Cloprednol
  - Meprednisone
  - Cortivazol
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**Study drug International non-proprietary name (INN) or common name**

AZATHIOPRINE

BELIMUMAB

BETAMETHASONE

CYCLOPHOSPHAMIDE

DEXAMETHASONE

HYDROCORTISONE

HYDROXYCHLOROQUINE

METHOTREXATE

METHYLPREDNISOLONE

MYCOPHENOLATE MOFETIL

PREDNISOLONE

RITUXIMAB

TACROLIMUS

VOCLOSPORIN

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**Anatomical Therapeutic Chemical (ATC) code**

(H02AB01) betamethasone

betamethasone

(H02AB02) dexamethasone

dexamethasone

(H02AB03) fluocortolone

fluocortolone

(H02AB04) methylprednisolone

methylprednisolone

(H02AB05) paramethasone

paramethasone

(H02AB06) prednisolone

prednisolone

(H02AB07) prednisone

prednisone

(H02AB08) triamcinolone

triamcinolone

(H02AB09) hydrocortisone

hydrocortisone

(H02AB10) cortisone

cortisone

(H02AB11) prednylidene

prednylidene

(H02AB12) rimexolone

rimexolone

(H02AB13) deflazacort

deflazacort

(H02AB14) cloprednol

cloprednol

(H02AB15) meprednisone

meprednisone

(H02AB17) cortivazol

cortivazol

(L01AA01) cyclophosphamide

cyclophosphamide

(L01BA01) methotrexate

methotrexate

(L01FA01) rituximab

rituximab

(L04AA06) mycophenolic acid

mycophenolic acid

(L04AA26) belimumab

belimumab

(L04AD01) ciclosporin

ciclosporin

(L04AD02) tacrolimus

tacrolimus

(L04AD03) voclosporin

voclosporin

(L04AX01) azathioprine

azathioprine

(L04AX03) methotrexate

methotrexate

(P01BA02) hydroxychloroquine

hydroxychloroquine

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### **Medical condition to be studied**

Systemic lupus erythematosus

## Population studied

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

The study population will include all individuals with a first diagnosis of SLE identified in the database during the patient selection period, which is between

01/01/2013 and 180 days prior to the end of available data in each database.

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### **Age groups**

- Infants and toddlers (28 days - 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
  - 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**

19900000

## Study design details

### **Data analysis plan**

Large scale patient level characterisation will be conducted. Medical condition and medication use history will be reported at any time and 365 days prior to index date, respectively. The number and percentage of patients receiving each of a pre specified list of SLE treatments and treatment combinations will be described per calendar year. Additionally, sunburst plots and Sankey diagrams will be used to describe treatment patterns and sequences over time. For the new user cohort, the index date is the initiation of SLE treatment after SLE diagnosis. Treatment duration, initial dose strength, cumulative dose, number of prescriptions will be estimated for new users of each SLE treatments at the ingredient level. For all continuous variables, mean with standard deviation and median with interquartile range will be reported. For all categorical analyses,

number and percentages will be reported. A minimum cell count of 5 will be used when reporting results, smaller counts reported as 5.

## Documents

### Study report

[DARWIN\\_EU\\_Study\\_Report\\_P2-C1-006\\_v2.0\\_final.pdf](#) (2.83 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)

Institut Municipal d'Assistència Sanitària Information System / Hospital del Mar / PSMAR / (Hospital del Mar Information System)

IQVIA Disease Analyzer Germany

The Information System for Research in Primary Care (SIDIAP)

Clinical Practice Research Datalink (CPRD) GOLD

Clinical Data Warehouse of the Bordeaux University Hospital

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### Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Other

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**Data sources (types), other**

Specialist care, Hospital linkage, Secondary care

## Use of a Common Data Model (CDM)

**CDM mapping**

Yes

**CDM Mappings**

**CDM name**

OMOP

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**CDM website**

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

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## 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