EULAR/ACR criteria for SLE

ReBioLup

Please fill in the individual criteria.
The total score will be calculated automatically.

Entry criterion

Antinuclear antibodies (ANA) at a titre of ≥1:80 on HEp-2 cells or an equivalent positive test (ever)

◯ Yes
◯ No

Additive criteria - Clinical domains

Do not count a criterion if there is a more likely explanation than SLE. Occurrence of a criterion on at least one occasion is sufficient.
SLE classification requires at least one clinical criterion and 10 points. Criteria do not need to occur simultaneously.

Constitutional

☐ Fever (2 points)

Constitutional domain score [automated]

_____

Haematological

☐ Leukopenia (3 points)
☐ Thrombocytopenia (4 points)
☐ Autoimmune haemolysis (4 points)

Haematological domain score [automated]

_____

Neuropsychiatric

☐ Delirium (2 points)
☐ Psychosis (3 points)
☐ Seizure (5 points)

Neuropsychiatric domain score [automated]

_____

Mucocutaneous

☐ Non-scarring alopecia (2 points)
☐ Oral ulcers (2 points)
☐ Subacute cutaneous or discoid lupus (4 points)
☐ Acute cutaneous lupus (6 points)

Mucocutaneous domain score [automated]

_____

Serosal

☐ Pleural or pericardial effusion (5 points)
☐ Acute pericarditis (6 points)

Serosal domain score [automated]

_____

Musculoskeletal	☐ Joint involvement (6 points)
Musculoskeletal domain score [automated]	_____
Renal	☐ Proteinuria > 0.5 g/24 hours (4 points) ☐ Renal biopsy-proven class II or V lupus nephritis (8 points) ☐ Renal biopsy-proven class III or IV lupus nephritis (10 points)
Renal domain score [automated]	_____

Additive criteria - Immunological domains

Do not count a criterion if there is a more likely explanation than SLE. Occurrence of a criterion on at least one occasion is sufficient.

SLE classification requires at least one clinical criterion and 10 points. Criteria do not need to occur simultaneously.

Antiphospholipid antibodies Fill in all that apply. The maximum score for this domain will not exceed 2 in the compulsional part.	☐ Anticardiolipin antibodies (2 points) ☐ Anti-β2-glycoprotein I antibodies (2 points) ☐ Lupus anticoagulant (2 points)
Antiphospholipid antibodies domain score [automated]	_____
Complement proteins	☐ Low C3 or low C4 (3 points) ☐ Low C3 and low C4 (4 points)
Complement proteins domain score [automated]	_____
SLE-specific autoantibodies Fill in all that apply. The maximum score for this domain will not exceed 6 in the compulsional part.	☐ Anti-dsDNA antibody (6 points) ☐ Anti-Sm antibody (6 points)
SLE-specific autoantibodies domain score [automated]	_____

Total score and outcome [automated]

Criteria total score _____

Patient fulfills criteria

Patient does not fulfill criteria

Demographics

ReBioLup

Consent Information

Date for signed consent

_____
(YYYY-MM-DD)

Contact Information

Date of birth

_____
(YYYY-MM-DD)

Date of SLE diagnosis

_____
(YYYY-MM-DD)

Sex

◯ Female
◯ Male

Ancestry

◯ Asian
◯ Black or African American
◯ Indigenous American
◯ White or Caucasian

Hispanic or Latino

◯ Hispanic or Latino
◯ Not Hispanic or Latino

Country of birth

_____

Highest level of education

◯ Less than a high school diploma
◯ High school
◯ University

Baseline items

ReBioLup

Smoking status

Smoking status
- ◯ Never smoked
- ◯ Former smoker
- ◯ Current smoker

Pack-years

_____

Year of cessation

_____
(YYYY)

Baseline-specific items

Height (cm)

_____
(cm)

Pre-LN S-creatinine (mg/dL)

_____
(mg/dL)

Date of pre-LN S-creatinine

_____
(YYYY-MM-DD)

Former medications (from SLE diagnosis until kidney biopsy; excluding LN treatment)

Glucocorticoids
- ◯ Yes
- ◯ No

IV Glucocorticoids
- ◯ Yes
- ◯ No

Oral Glucocorticoids
- ◯ Yes
- ◯ No

Antimalarial agents
- ◯ Yes
- ◯ No

Antimalarials (specify)
Fill in all that apply
- ☐ Hydroxychloroquine
- ☐ Chloroquine
- ☐ Mepacrine
- ☐ Other antimalarial agents

Methotrexate
- ◯ Yes
- ◯ No

Azathioprine
- ◯ Yes
- ◯ No

Mycophenolic acid	◯ Yes ◯ No
Cyclosporine A	◯ Yes ◯ No
Tacrolimus	◯ Yes ◯ No
Other immunosuppressants	◯ Yes ◯ No
Other immunosuppressants (specify)	_____
Belimumab	◯ Yes ◯ No
Rituximab	◯ Yes ◯ No
Other biologics	◯ Yes ◯ No
Other biologics (specify)	_____
Small molecules	◯ Yes ◯ No (e.g. JAK inhibitors)
Small molecules (specify)	_____
ACE inhibitors	◯ Yes ◯ No
Angiotensin II receptor blockers	◯ Yes ◯ No
NSAIDs (regular use for periods > 3 months)	◯ Yes ◯ No (regular use)

Visit items

ReBioLup

Date of visit

_____
(YYYY-MM-DD)

Clinical data

Weight (kg)

_____
(kg)

S-creatinine (mg/dL)

_____
(mg/dL)

Urine protein/creatinine ratio (UPCR; g/g)

_____
(g/g)

24-h urinary protein excretion (mg/24h)

_____
(mg/24h)

Serum albumin (g/dL)

_____
(g/dL)

Systolic blood pressure (mm Hg)

_____
(mm Hg)

Diastolic blood pressure (mm Hg)

_____
(mm Hg)

Positive anti-dsDNA

As per local laboratory cut-off

◯ Yes
◯ No

C3 level (g/L)

_____
(g/L)

Low C3

As per local laboratory cut-off

◯ Yes
◯ No

C4 level (g/L)

_____
(g/L)

Low C4

As per local laboratory cut-off

◯ Yes
◯ No

Current medications

Glucocorticoids
◯ Yes
◯ No

IV Glucocorticoids
◯ Yes
◯ No

Methylprednisolone equivalent dose (cumulative for the current treatment; mg)
_____
(mg)

Oral Glucocorticoids
◯ Yes
◯ No

Prednisone equivalent dose (mg/day)
_____
(mg/day)

Antimalarial agents
◯ Yes
◯ No

Antimalarials (specify)

Fill in all that apply
☐ Hydroxychloroquine
☐ Chloroquine
☐ Mepacrine
☐ Other antimalarial agents

Hydroxychloroquine dose (mg/day)
_____
(mg/day)

Chloroquine dose (mg/day)
_____
(mg/day)

Mepacrine dose (mg/day)
_____
(mg/day)

Name of other antimalarial drug (if not in the list)
_____

Dose of other antimalarial drug (mg/day)
_____
(mg/day)

Methotrexate
◯ Yes
◯ No

Methotrexate dose (mg/week)
_____
(mg/week)

Azathioprine
◯ Yes
◯ No

Azathioprine dose (mg/day)

_____
(mg/day)

Mycophenolic acid

◯ Yes
◯ No

Mycophenolate mofetil equivalent dose (mg/day)

_____
(mg/day)

Cyclosporine A

◯ Yes
◯ No

Cyclosporine A dose (mg/day)

_____
(mg/day)

Tacrolimus

◯ Yes
◯ No

Tacrolimus dose (mg/day)

_____
(mg/day)

Other immunosuppressants

◯ Yes
◯ No

Other immunosuppressants (specify)

_____

Belimumab

◯ Yes
◯ No

Belimumab administration

◯ Intravenous
◯ Subcutaneous

Rituximab

◯ Yes
◯ No

Other biologics

◯ Yes
◯ No

Other biologics (specify)

_____

Small molecules

◯ Yes
◯ No
(e.g. JAK inhibitors)

Small molecules (specify)

_____

ACE inhibitors	◯ Yes ◯ No
Angiotensin II receptor blockers	◯ Yes ◯ No

Adverse Events or Special Situation report form

Has the patient experienced a serious adverse event? Definition of Serious Adverse Event (SAE): Any untoward medical occurrence that, for any medication at any dose: · results in death. · is life-threatening. · requires inpatient hospitalisation* or prolongation of existing hospitalisation. · results in persistent or significant disability/incapacity. · is a congenital anomaly/birth defect. · is medically significant or requires intervention to prevent one of the outcomes listed above. * Hospitalisation is defined as in-patient hospital admission for one or more days associated with an Adverse Event which occurs or worsens after the subject is screened into the clinical study or after a patient has taken a medication. Thus: attendance/treatment at an emergency room/outpatient department does not meet hospitalisation criteria unless the attendance/treatment was due to a SAE as described above.	◯ Yes ◯ No

Has a Special Situation Report (with or without adverse events) been identified as described below?	◯ Yes ◯ No

· Medication Error: an unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient (including potential medication errors or intercepted medication errors).

· Overdose: the administration of a quantity of a medicinal product given per administration or cumulatively, which is above the maximum recommended dose according to the authorised product information. Clinical judgment should always be applied.

· Pregnancy exposure: situations where the embryo or foetus may have been exposed to a medicinal product(s), either through maternal exposure or transmission of a medicinal product via semen following paternal exposure

· Breastfeeding: This refers to a situation in infants following exposure to a medicinal product from breast milk.

Suspect Adverse Reaction Report

I. Reaction information

Reaction onset

_____

Describe reaction(s) (including relevant tests/lab data)

_____

Check all appropriate boxes to adverse reactions

- ☐ Patient died
- ☐ Involved or prolonged inpatient hospitalisation
- ☐ Involved persistence or significant disability or incapacity
- ☐ Life-threatening

II. Suspect drug(s) information

Suspect drug(s) (include generic name)

_____

Daily dose(s)

_____

Route(s) of administration

_____

Indication(s) for use

_____

Therapy dates (from/to)	_____ (From: (D-M-Y) To: (D-M-Y))
Therapy duration	_____
Did reaction abate after stopping drugs?	◯ Yes ◯ No ◯ NA
Did reaction reappear after re-introduction?	◯ Yes ◯ No ◯ NA

III. Concomitant drug(s) and history

Concomitant drug(s) and dates of administration (exclude those used to treat reaction)	_____
Other relevant history (e.g. diagnostics, allergics, pregnancy with last month of period, etc.)	_____

IV. Manufacturer information

Name and address of manufacturer	_____
Manufacturer control number	_____
Date recieved by manufacturer	_____
Report source	◯ Study ◯ Litterature ◯ Health professional
Date of this report	_____
Report type	◯ Initial ◯ Follow-up

Product complaint form

Has a product complaint been identified as described below? Any written or oral information received from a complainant that alleges deficiencies related to identity, quality, safety, strength, purity, reliability, durability, effectiveness, or performance of a product after it has been released and distributed to the commercial market or clinical trial.	◯ Yes ◯ No
Complete fields	
Name of product:	_____
As many details as possible, product name, configuration, Dosage form, strength: free text additional details.	_____
Batch number	_____ (If not available, state "I don't know")
Number of units affected	_____ (If not available, state "I don't know")
Country where product was purchased:	_____
Is the product available for return?	◯ Yes ◯ No ◯ I don't know
What was wrong with the product? Please describe.	_____
What was wrong with the product? Please attach photos if available.	
How is it different from "normal"? Please add a detailed description of the defect (e.g. appearance, damage, leakage).	_____
Describe at what point was the defect or issue discovered (e.g. when opening the box, before the administration, after the administration, at which handling step according to instructions of use or patient information leaflet)	_____
Personal details of reporter	_____ (Name, address, email, phone number)

Kidney histopathology - Baseline

ReBioLup

2003 ISN/RPS class
Fill in all that apply

- ☐ III
- ☐ IV
- ☐ V

2003 ISN/RPS active and/or chronic lesions
Fill in all that apply

- ☐ Active lesions (A)
- ☐ Chronic lesions (C)

2003 ISN/RPS segmenal or global lesions

- ◯ Segmental (S)
- ◯ Global (G)

NIH Activity Index Score

_____
(of a total of 24 points)

NIH Chronicity Index Score

_____
(of a total of 12 points)

Presence of patterns consistent with APSN

APSN: antiphospholipid syndrome-associated nephropathy

- ◯ Yes
- ◯ No

Specify APSN patterns
APSN: antiphospholipid syndrome-associated nephropathy

_____

Kidney histopathology - Month 12

ReBioLup

2003 ISN/RPS class
Fill in all that apply

- ☐ I
- ☐ II
- ☐ III
- ☐ IV
- ☐ V

2003 ISN/RPS active and/or chronic lesions
Fill in all that apply

- ☐ Active lesions (A)
- ☐ Chronic lesions (C)

2003 ISN/RPS segmenal or global lesions

- ◯ Segmental (S)
- ◯ Global (G)

NIH Activity Index Score

_____
(of a total of 24 points)

NIH Chronicity Index Score

_____
(of a total of 12 points)

Presence of patterns consistent with APSN

APSN: antiphospholipid syndrome-associated nephropathy

- ◯ Yes
- ◯ No

Specify APSN patterns
APSN: antiphospholipid syndrome-associated nephropathy

_____

SLEDAI-2K

ReBioLup

SLEDAI-2K

Systemic Lupus Erythematosus Disease Activity Index 2000

Please click "yes" if the descriptor is present at the time of the visit or has been present in the preceding 10 days.
Empty descriptors will be considered absent, not missing values.
The final SLEDAI-2K score will be calculated automatically.

Central nervous system

Seizure
Recent onset.
Exclude metabolic, infectious, or drug causes.

☐ Yes
(Weight: 8 points)

Psychosis
Altered ability to function in normal activity due to severe disturbance in the perception of reality. Include hallucinations, incoherence, marked loose associations, impoverished thought content, marked illogical thinking, bizarre, disorganised, or catatonic behavior.
Exclude uraemia and drug causes.

☐ Yes
(Weight: 8 points)

Organic brain syndrome
Altered mental function with impaired orientation, memory, or other intellectual function, with rapid onset and fluctuating clinical features, inability to sustain attention to environment, plus at least 2 of the following: perceptual disturbance, incoherent speech, insomnia or daytime drowsiness, or increased or decreased psychomotor activity.
Exclude metabolic, infectious, or drug causes.

☐ Yes
(Weight: 8 points)

Visual disturbance
Retinal changes of SLE. Include cytoid bodies, retinal haemorrhages, serous exudates or haemorrhages in the choroids, or optic neuritis.
Exclude hypertension, infection, or drug causes.

☐ Yes
(Weight: 8 points)

Cranial nerve disorder
New onset of sensory or motor neuropathy involving cranial nerves.

☐ Yes
(Weight: 8 points)

Lupus headache
Severe, persistent headache; may be migrainous, but must be non-responsive to narcotic analgesia.

☐ Yes
(Weight: 8 points)

Cerebrovascular accident
New onset of cerebrovascular accident(s).
Exclude arteriosclerosis.

☐ Yes
(Weight: 8 points)

SLEDAI-2K central nervous system (CNS) score [automated]

_____

Vascular

Vasculitis
Ulceration, gangrene, tender finger nodules, periungual infarction, splinter haemorrhages, or biopsy or angiogram proof of vasculitis.

☐ Yes
(Weight: 8 points)

SLEDAI vascular score [automated]

_____

Musculoskeletal

Arthritis
≥ 2 joints with pain and signs of inflammation (i.e. tenderness, swelling, or effusion).

☐ Yes
(Weight: 4 points)

Myositis
Proximal muscle aching/weakness, associated with elevated creatine, phosphokinase/aldolase or electromyogram changes, or a biopsy showing myositis.

☐ Yes
(Weight: 4 points)

SLEDAI-2K musculoskeletal score [automated]

_____

Renal

Urinary casts
Haemogranular or red blood cell casts.

☐ Yes
(Weight: 4 points)

Haematuria
> 5 red blood cells/high power field.
Exclude stone, infection, or other cause.

☐ Yes
(Weight: 4 points)

Proteinuria
> 0.5 g/24 hours.

☐ Yes
(Weight: 4 points)

Pyuria
> 5 white blood cells/high power field.
Exclude infection.

☐ Yes
(Weight: 4 points)

SLEDAI-2K renal score [automated]

_____

Dermal

Rash
Inflammatory type rash.

☐ Yes
(Weight: 2 points)

Alopecia
Abnormal, patchy or diffuse loss of hair.

☐ Yes
(Weight: 2 points)

Mucosal ulcers
Oral or nasal ulcerations.

☐ Yes
(Weight: 2 points)

SLEDAI-2K dermal score [automated]

_____

Serosal

Pleurisy
Pleuritic chest pain with pleural rub or effusion, or pleural thickening.

☐ Yes
(Weight: 2 points)

Pericarditis
Pericardial pain with at least one of the following: rub, effusion or electrocardiogram or echocardiogram confirmation.

☐ Yes
(Weight: 2 points)

SLEDAI-2K serosal score [automated]

_____

Immunological

Low complement
Decrease CH50, C3, or C4 below the lower limit of normal for testing laboratory.

☐ Yes
(Weight: 2 points)

Increased DNA binding
Increased DNA binding by Farr assay above normal range for testing laboratory.

☐ Yes
(Weight: 2 points)

SLEDAI-2K immunological score [automated]

_____

Constitutional

Fever
> 38° C.
Exclude infectious cause.

☐ Yes
(Weight: 1 point)

SLEDAI-2K constitutional score [automated]

_____

Haematological

Thrombocytopenia
< 100,000 platelets/µL.
Exclude drug causes.

☐ Yes
(Weight: 1 point)

Leukopenia
< 3,000 white blood cells/µL.
Exclude drug causes.

☐ Yes
(Weight: 1 point)

SLEDAI-2K haematological score [automated]

_____

Total SLEDAI-2K score [automated]

Total SLEDAI-2K score

_____

Clinical SLEDAI-2K score

_____

SLICC/ACR Damage Index (SDI)

ReBioLup

SLICC/ACR Damage Index (SDI)

Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index

Damage occurring since diagnosis of SLE, ascertained by clinical assessment and present for ≥ 6 months unless otherwise stated. Repeat episodes have to be ≥ 6 months apart to score 2. The same lesion cannot be scored twice. Note that you only need to check the box "1 point" when a descriptor is present; leave empty otherwise. Exceptions are descriptors that can generate scores of > 1. These fields are required.

Ocular

Either eye, by clinical assessment

Any cataract ever	☐ 1 point
Retinal change or optic atrophy	☐ 1 point
SDI ocular score [automated]	_____

Neuropsychiatric

Cognitive impairment (e.g. memory deficit, difficulty with calculation, poor concentration, difficulty in spoken or written language, impaired performance level) or major psychosis	☐ 1 point
Seizures requiring therapy for 6 months	☐ 1 point
Cerebral vascular accident ever (score 2 if > 1), resection not for malignancy	◯ 0 points ◯ 1 point ◯ 2 points (Please note that this field is required)
Cranial or peripheral neuropathy (excluding optic)	☐ 1 point
Transverse myelitis	☐ 1 point
SDI neuropsychiatric score [automated]	_____

Renal

Estimated or measured GFR < 50%	☐ 1 point
Proteinuria ≥ 3.5 g/24 hours (score 1) or end-stage renal disease, regardless of dialysis or transplantation (score 3)	◯ 0 points ◯ 1 point ◯ 3 points (Please note that this field is required)
SDI renal score [automated]	_____

Pulmonary

Pulmonary hypertension (right ventricular prominence, or loud P2)	☐ 1 point
Pulmonary fibrosis (physical and X-ray)	☐ 1 point
Shrinking lung (X-ray)	☐ 1 point
Pleural fibrosis (X-ray)	☐ 1 point
Pulmonary infarction (X-ray) or resection not for malignancy	☐ 1 point
SDI pulmonary score [automated]	_____

Cardiovascular

Angina or coronary artery bypass	☐ 1 point
Myocardial infarction ever (score 2 if > 1)	◯ 0 points ◯ 1 point ◯ 2 points (Please note that this field is required)
Cardiomyopathy (ventricular dysfunction)	☐ 1 point
Valvular disease (diastolic murmur, or a systolic murmur > 3/6)	☐ 1 point
Pericarditis (for ≥ 6 months) or pericardiectomy	☐ 1 point
SDI cardiovascular score [automated]	_____

Peripheral vascular

Claudication (for ≥ 6 months)	☐ 1 point
Minor tissue loss (pulp space)	☐ 1 point
Significant tissue loss ever (e.g. loss of digit or limb, resection) (score 2 if > 1)	◯ 0 points ◯ 1 point ◯ 2 points (Please note that this field is required)
Venous thrombosis with swelling, ulceration, or venous stasis	☐ 1 point
SDI peripheral vascular score [automated]	_____

Gastrointestinal

Infarction or resection of bowel (below duodenum), spleen, liver or gall bladder ever (score 2 if > 1)	◯ 0 points ◯ 1 point ◯ 2 points (Please note that this field is required)
Mesenteric insufficiency	☐ 1 point
Chronic peritonitis	☐ 1 point
Stricture or upper gastrointestinal tract surgery ever	☐ 1 point
Pancreatic insufficiency requiring enzyme replacement or with pseudocyst	☐ 1 point
SDI gastrointestinal score [automated]	_____

Musculoskeletal

Muscular atrophy or weakness	☐ 1 point
Deforming or erosive arthritis (including reducible deformities, excluding avascular necrosis)	☐ 1 point
Osteoporosis with fracture or vertebral collapse (excluding avascular necrosis)	☐ 1 point

Avascular necrosis (score 2 if > 1)	◯ 0 points ◯ 1 point ◯ 2 points (Please note that this field is required)
Osteomyelitis	☐ 1 point
Ruptured tendons	☐ 1 point
SDI musculoskeletal score [automated]	_____

Skin

Scarring chronic alopecia	☐ 1 point
Skin ulceration (excluding thrombosis) for ≥ 6 months	☐ 1 point
SDI skin score [automated]	_____

Premature gonadal failure

Premature gonadal failure	☐ 1 point
SDI premature gonadal failure score [automated]	_____

Diabetes

Diabetes (regardless of treatment)	☐ 1 point
SDI diabetes score [automated]	_____

Malignancy

Malignancy (score 2 if > 1 site) Exclude dysplasia.	◯ 0 points ◯ 1 point ◯ 2 points (Please note that this field is required)
SDI malignancy score [automated]	_____

Total SLICC/ACR Damage Index (SDI) score [automated]

Total SDI score _____

Exit

ReBioLup

Study Completion Information

Has the patient completed the study?	◯ Yes ◯ No (Yes: 60 months of follow-up; No: early withdrawal)
Put a date if the patient withdrew from ReBioLup	_____ (YYYY-MM-DD)
Reason why the patient withdrew from the study	◯ Non-compliance ◯ Did not wish to continue in the study ◯ Other
Please specify the reason	_____
Date of study completion	_____ (YYYY-MM-DD)

General Comments

Comments	_____

Sample collection

ReBioLup

Serum sample collected	◯ Yes ◯ No
Provide the date for sample collection	_____ (YYYY-MM-DD)
Urine sample collected	◯ Yes ◯ No
Provide the date for sample collection	_____ (YYYY-MM-DD)