

Annex

Data abstraction format

Part I: Socio-demographic characteristics

Patient MRN: _____

1. Sex Male Female
2. If female, Pregnant Non-pregnant Breast feeding
3. Age at LN diagnosis (year): _____
4. Place of residence Rural Urban
5. Smoking status Smoker Non-smoker Not documented

Part II: Baseline patient clinical presentation

1. Initial confirmation/date of diagnosis of LN (SLE with renal involvement) _____ date/month/year
2. Clinical presentation
 - High blood pressure
 - Periorbital puffiness
 - Edema, Specify: _____
 - Other non-specific symptoms: _____
3. Weight (kg) at diagnosis: _____
4. Blood pressure (BP) at baseline: _____ mmHg, and at end of the study: _____ mmHg
5. Lupus class at first biopsy: I II III IV V VI
6. Repeated biopsy class: _____

Part III: Medical history and LN complications

1. Presence of medical history Yes No

2. Presence of LN complications Yes No

If the response for the above question is yes, which of the following medical history or LN complications? (Can tick more than once)

Comorbid conditions and LN complication	Yes	No
Any intrinsic renal disease		
AKI (acute tubular necrosis, interstitial nephritis)		
Nephrotic syndrome		
Others(specify):		
Any non-renal comorbidities		
Antiphospholipid syndrome (APS)		
Lupus cerebritis		
Discoid lupus erythematosus		
Drug induced lupus		
Infection-related glomerulonephritis		
Others(specify):		
Complications		
CKD/ESRD		
Others (thrombotic microangiopathy (TMA), cardiovascular complications, malignancies)		

Part IV: Baseline and end of study pertinent laboratory investigations

1. Complete blood count (CBC)

Parameters	WBC	RBC	HGB	HCT	PLT	ESR
Baseline						
End of study						

2. Renal function tests (RFT)

Parameters	Serum creatinine (SCr)	Urea (BUN)	Estimated glomerular filtration (eGFR)
Baseline			
6 th month			
End of study			

3. Urine analysis

Parameters	24-hr Urine Protein		Urine Protein	Urine WBC	Urine RBC	Urine bacteria	Urinary casts	Serum albumin	UPCR
	Non pregnant	Pregnant							
Baseline									
6 th month									
End of study									

4. Serum electrolytes

Parameters	Sodium(Na)	Potassium(K)	Chloride(CL)	Calcium total	Phosphorus(Phos)
Baseline					
End of study					

5. Immunological investigations

Parameters	ANA	Anti-dsDNA	C3 Level	C4 Level	ANCA	RF
Baseline						
End of study						

6. Lupus anticoagulants (Lupus inhibitors)

Parameters	Lupus anticoagulants(LA)				
	Beta 2 Glycoprotein1-IgG	Beta 2 Glycoprotein1-IgM	LA1 screen	LA2 confirm	Ratio (LA1/LA2)
Baseline					
End of study					

7. Other antibodies tests

Parameters	Cardiolipin antibodies, IgG, IgM	Phospholipid antibody (APA), IgG, IgM	Beta 2 Glycoprotein1, IgA
Baseline			
End of study			

8. Coagulation profiles

Parameters	PT	INR	PTT
Baseline			
End of study			

9. Lipid profiles

Parameters	Total cholesterol	TG	HDL	LDL
Baseline				
End of study				

10. Liver function tests

Parameters	ALT	AST	ALP
Baseline			
End of study			

11. Glucose levels

Parameters	RBS	FBS	HgA1C
Baseline			
End of study			

Part V: Hospitalization events

1. Hospitalization events due to LN. Yes No
2. Reason for admission; Due to LN flare/relapse Due to other comorbidities
3. Presence/development of infection Yes No,

3.1 If yes for no. 3 what antibiotics are given: _____

Part VI: Medication management practice of LN complications and comorbidities (LN follow up management)

1. List of prescribed medications

Type of medications	Dose and frequency	Start date	Stop date	Yes	No
Induction therapy/phase					
Prednisolone					
Methylpredinsolone					
Cyclophosphamide					
Mycophenolate mofetil (MMF)					
Azathioprine					
Tacrolimus					
Rituximab					
Maintenance therapy/phase					
Prednisolone					
Mycophenolate mofetil (MMF)					
Azathioprine					
Tacrolimus					
Kidney protective regimens					
ACEIs					
ARBs					
Other medications (adjunctive treatments)					
Chloroquine or Hydroxychloroquine					
Others (specify if pertinent to LN):					

2. Total duration of treatment for LN up to end of data collection in months: _____

Part VII: If any medications are adjusted/stopped/changed during the study period,

Medication name	Reason(ADR, relapse/flare, pregnancy, availability/cost issue)	Description of the ADR if reported

Part VIII: Outcome measures/end points

1. Complete renal remission (CR)

1.1. Decline or reduction in proteinuria to < 0.5g/g measured as UPCR from a 24-hr urine collection: Yes No

1.2. Stabilization or improvement in kidney function (\pm 10-15% of baseline): Yes No

2. Partial renal remission (PR)

2.1. Reduction in proteinuria by at least 50% and to <3g/g measured as UPCR from a 24-hr urine collection : Yes No

2.2. Stabilization or improvement in kidney function (\pm 10-15% of baseline): Yes No

3. No response/non responders (NR)

3.1. Failure to achieve a complete or partial remission: Yes No

3.1.1. Worsening of kidney function: Yes No

3.1.2. Re-biopsy (activity present or absent): Yes No

4. Worse outcomes

4.1. Progression to ESRD: Yes No

4.2. All-cause mortality: Yes No