

CENTRE ID



**BILAG Biologics Register**  
 Consultant Baseline Questionnaire

PATIENT ID









d d m m y y y y

Clinic date at BASELINE:









**NB: Please complete the baseline to correspond to the clinic visit where the patient received their registration therapy**

**SLE DETAILS**

**Please complete either the ACR criteria for SLE or the SLICC Criteria for SLE**

**1a. ACR Criteria (please tick each criterion that has ever applied):**

<input type="checkbox"/>	Malar rash
<input type="checkbox"/>	Photosensitivity
<input type="checkbox"/>	Discoid rash
<input type="checkbox"/>	Oral ulceration
<input type="checkbox"/>	Arthritis
<input type="checkbox"/>	Serositis
<input type="checkbox"/>	CNS involvement
<input type="checkbox"/>	Renal involvement
<input type="checkbox"/>	Haematological involvement
<input type="checkbox"/>	ANA
<input type="checkbox"/>	Immunological disorder

**1b. SLICC SLE Criteria (please tick each criterion that has ever applied):**

*(Requirements ≥4 criteria (≥1 clinical and 1 lab criteria) OR biopsy proven lupus nephritis with positive ANA or Anti-DNA)*

**Clinical Criteria**

<input type="checkbox"/>	Acute Cutaneous Lupus
<input type="checkbox"/>	Chronic Cutaneous Lupus
<input type="checkbox"/>	Oral or nasal ulcers
<input type="checkbox"/>	Non-scarring alopecia
<input type="checkbox"/>	Arthritis
<input type="checkbox"/>	Serositis
<input type="checkbox"/>	Renal
<input type="checkbox"/>	Neurological
<input type="checkbox"/>	Haemolytic anaemia
<input type="checkbox"/>	Leukopenia
<input type="checkbox"/>	Thrombocytopenia (<100,000/mm <sup>3</sup> )

**Immunological Criteria**

<input type="checkbox"/>	ANA
<input type="checkbox"/>	Anti-DNA
<input type="checkbox"/>	Anti-Sm
<input type="checkbox"/>	Antiphospholipid Ab
<input type="checkbox"/>	Low complement (C3, C4, CH50)
<input type="checkbox"/>	Direct Coombs' test (do not count the presence of haemolytic anaemia)

	DD	MM	YYYY
2. Date of first criteria fulfilled:			

3. Date of SLE diagnosis (4 <sup>th</sup> criteria fulfilled):			
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4a. Affected organ system(s):

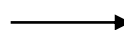

4b. Reason for prescribing registration therapy:


5. Does the patient have a family history of SLE?  
(i.e. first-degree relative such as parent, sibling or child)

Yes	
No	
Don't know	

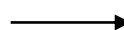
Is the patient scheduled to start:

Biologic therapy (i.e. treatment group)?

Go to 6)

Immunosuppressant therapy (i.e. control group)?



Go to 7)

**BIOLOGIC THERAPY**

6. Please tick which biologic therapy (please use the trade name of the therapy, e.g. Mabthera or Truxima):

<input type="checkbox"/>	Mabthera (Rituximab)	<input type="checkbox"/>	Abatacept
<input type="checkbox"/>	Truxima (Rituximab)	<input type="checkbox"/>	Ocrelizumab
<input type="checkbox"/>	Benlysta (Belimumab)	<input type="checkbox"/>	Actemra/RoActemra (Tocilizumab)
<input type="checkbox"/>	Other biologic or biosimilar (details):		

Please provide batch number of the first dose: \_\_\_\_\_ (tick if unknown) ☐

Is the patient switching from an originator i.e. Mabthera directly to a biosimilar of the same product i.e. Truxima? ☐ Yes ☐ No

If yes, please provide the reason for the switch:

<input type="checkbox"/>	Clinical Indication
<input type="checkbox"/>	Patient Choice
<input type="checkbox"/>	Cost Factors
<input type="checkbox"/>	Other:

Comments:

Is the drug given as a regular injection/infusion (e.g. abatacept, Enbrel, Benlysta)?

Yes	<input type="checkbox"/>	→	Go to 6b)
No	<input type="checkbox"/>	→	Go to 6c)

6b. What is the frequency of the injection/infusion?

☐ Daily ☐ Weekly ☐ Fortnightly ☐ Monthly

☐ Every 3 months ☐ Other interval (specify) \_\_\_\_\_

What is the dose of each injection/infusion? \_\_\_\_\_ mg

D D M M Y Y Y Y

Please indicate date this course started/will start

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Date this course stopped (if applicable)

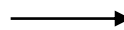
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Please indicate reason for stopping using the code below: \_\_\_\_\_

Discontinuation code: 1 = Inefficacy; 2 = remission; 3 = Adverse events; 4 = Other\*

6c. Is the drug given as an intermittent/episodic therapy (e.g. Mabthera, ocrelizumab etc.)?

Yes

☐

Continue with this section

No

☐

Go to question 8

Please indicate the dates of each infusion / injection in this course:

D	D	M	M	Y	Y	Y	Y
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Please also indicate the infusion/injection dose:

\_\_\_\_\_ mg

Has the patient a contraindication or lack of response that excludes future use of this agent?

Please indicate using the code below: \_\_\_\_\_

Discontinuation code: 1 = Inefficacy; 2 = remission; 3 = Adverse events; 4 = Other\*

Did the patient receive cyclophosphamide with their biologic therapy?

Yes

☐

No

☐

If Yes:

Dates of cyclophosphamide treatment:

D	D	M	M	Y	Y	Y	Y	D	D	M	M	Y	Y	Y	Y
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Dose of cyclophosphamide:

\_\_\_\_\_

Does the patient remain on background immunosuppressants?

Yes

☐

No

☐

\*\*\*Please ensure the information is provided in the relevant section of Qu 9\*\*\*

## IMMUNOSUPPRESSANT THERAPY

7. Please indicate which immunosuppressant the patient has just started or is scheduled to start:

<input type="checkbox"/> Azathioprine	<input type="checkbox"/> I.V. Cyclophosphamide	<input type="checkbox"/> Cyclophosphamide P.O.
<input type="checkbox"/> Cyclosporin A	<input type="checkbox"/> Mycophenolate Mofetil	
<input type="checkbox"/> Other	_____	

7b. What is the frequency of the dose?

<input type="checkbox"/> Daily	<input type="checkbox"/> Weekly	<input type="checkbox"/> Fortnightly	<input type="checkbox"/> Monthly
<input type="checkbox"/> Every 3 months	<input type="checkbox"/> Other interval (specify)	_____	

What is the average dose?

\_\_\_\_\_ mg

D D M M Y Y Y Y

Please indicate date this course started/will start

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Date this course stopped (if applicable)

--	--	--	--	--	--	--	--

Please indicate reason for stopping using the code below:

Discontinuation code: 1 = Inefficacy; 2 = remission; 3 = Adverse events; 4 = Other\*

## 8. CONCOMITANT THERAPY:

### Current Steroids:

We would like to record accurately and comprehensively the doses of steroids received by the patient, allowing for constant doses and periods of tapering doses

**Current oral steroids:** Yes ☐ → Current steroid preparation \_\_\_\_\_  
No ☐

1 = Prednisolone; 2 = Prednisone; 3 = Dexamethasone; 4 = Methylprednisolone; 5 = Deflazacort; 6 = Hydrocortisone; 7 = Budesonide; 8 = Other

Date started this **course** (dd/mm/yy) \_\_\_\_\_

Current steroid dose \_\_\_\_\_ mg/day

Date started this **particular** dose (dd/mm/yy) \_\_\_\_\_

**Usual** dose since this course started \_\_\_\_\_ mg/day

**Highest** dose in this course \_\_\_\_\_ mg/day

**Current pulse steroids:** Yes ☐ → Current IV steroid preparation \_\_\_\_\_  
No ☐

1 = Methylprednisolone; 2 = Hydrocortisone; 3 = Other

Date started this course (dd/mm/yy) \_\_\_\_\_

Number of pulses \_\_\_\_\_

Dose per pulse \_\_\_\_\_ mg

**Current IM steroids:** Yes ☐ → Current IM steroid preparation \_\_\_\_\_  
No ☐

1 = Methylprednisolone; 2 = Triamcinolone; 3 = other

Date started this course (dd/mm/yy) \_\_\_\_\_

Number of IM injections in this course \_\_\_\_\_

Dose \_\_\_\_\_ mg/injection

**PREVIOUS THERAPIES:**

**Steroids:** Please indicate whether the patient has ever had previous courses of:

☐ Oral steroids      ☐ Pulse steroids      ☐ IM steroids

**Antimalarials:** Please indicate whether the patient has ever taken any of the following antimalarials:

☐ Hydroxychloroquine      ☐ Chloroquine      ☐ Mepacrine  
☐ Other (please specify) \_\_\_\_\_

**Immunosuppressants:** Please indicate whether the patient has ever taken any of the following immunosuppressants

☐ Azathioprine      ☐ I.V. Cyclophosphamide      ☐ Cyclophosphamide P.O.  
☐ Cyclosporin A      ☐ Mycophenolate Mofetil      ☐ Methotrexate  
☐ Lefluonamide      ☐ Other \_\_\_\_\_

**Biologic therapy**

Please indicate whether the patient has ever had previous courses of biologic drugs. For intermittent therapies (e.g. rituximab) please list all courses:

Biologic	Date started	Date stopped	Dose	Frequency of dose	Reason for stopping

**Discontinuation code: 1 = Inefficacy; 2 = remission; 3 = Adverse events; 4 = Other\***

## 9. Current Medication:

	Yes	No	Don't know	Year started	Details where indicated
Calcium Supplement.....					
Vitamin D.....					
Bisphosphonates.....					
Proton-pump inhibitors.....					
Folic acid supplements.....					
Low-dose amitriptyline.....					
Anti-depressants (full dose).....					
Warfarin / other anticoagulants..... (please specify)					
Aspirin.....					
Clopidogrel.....					
Combined oral contraceptive pill...					
Progesterone only pill.....					
ACE – I.....					
ARB.....					
Thyroxine.....					
B12 Supplements.....					

Please list the patient's current medication, not already mentioned, for any indication.  
Please include all Concurrent Immunosuppressant details not already recorded.

Medication	Dose	Frequency of dose	Date started



**10. Co-morbidities and risk factors: Has the patient ever had (i.e. required treatment for) any of the following illnesses**

	Yes	No	Don't know	Year diagnosed			
Hypertension.....							
Angina.....							
Heart attack.....							
Stroke.....							
Epilepsy.....							
Asthma.....							
Chronic bronchitis/emphysema.....							
Peptic ulcer.....							
Liver disease.....							
Hepatitis.....							
Abnormal LFTs.....							
Demyelination.....							
Diabetes.....							
Thyroid disease.....							
Depression.....							
Blood dyscrasia.....							
Immunodeficiency syndromes.....							
Renal disease (non-lupus related).....							
Cancer							

If patient has **ever** had cancer, please specify site(s):

Chronic Kidney Disease (CKD).....

If yes, current stage of CKD: (please circle).

Stage	GFR (mls/min)
I	90+
II	60-89
III A	45-59
III B	30-44
IV	15-29
V	<15 or on dialysis

Other co-morbidity not listed.....Year of onset: .....

**11. Risk factors for infection: Has the patient ever had / required treatment for any of the following**

	Yes	No	Don't know	Year of onset (most recent if applicable)			
Hepatitis B.....							
Hepatitis C.....							
Latent Tuberculosis.....							
Leg Ulcers.....							
Indwelling Catheter.....							
PIC catheter.....							
Hickman line.....							
Bronchiectasis.....							
Surgical splenectomy.....							
Hyposplenism.....							
Other.....							

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**12. Vaccination history**

Vaccination	Date of most recent vaccination	
Pneumococcal		
Influenza		
Haemophilus Influenzae B		
Meningococcal C		
BCG scar present?	Yes	No

**Covid-19 Vaccinations:**

	Yes	No	Don't know
<b>13a. Has the patient ever had a Covid-19 vaccination?</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>b. Did the patient have both doses?</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>c. Date of most recent dose (approx. if necessary):</b>	<input type="text"/>		(DD/MM/YYYY)
<b>d. Covid-19 vaccine brand:</b>	<input type="checkbox"/> Pfizer/Biontech, <input type="checkbox"/> Oxford/Astra Zeneca <input type="checkbox"/> Moderna, <input type="checkbox"/> Unknown <input type="checkbox"/> Other not listed: .....		

**14. Blood pressure: what is the patient's current blood pressure (i.e. at the time the biologic agent was started)?**

Systolic				mm
Diastolic				mm

**15. Height and weight: what is the patient's current height and weight (i.e. at the time the biologic agent was started)?**

Weight				kg
Height				cm

**16. Waist circumference: what is the patient's current waist circumference (i.e. at the time the biologic agent was started)?**

Waist circumference				cm
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**17. Please complete the following laboratory values (recent i.e. within the last 6 months)**

**Auto antibody profiles**

	Present ever?		Date checked	Titre (if applicable) or positive/negative		Titre	Lab normal range
	Y	N		+ve	-ve		
ANA.....							
Ds DNA.....							
Ro.....							
La.....							
Sm.....							
RNP.....							
Scl-70.....							
Centromere.....							

	Titre	Lab normal range	Date checked
Complement fractions:			
C3 (mg/l)			
C4 (mg/l)			
Total cholesterol (mmol/L)			
HDL (mmol/L)			
Fasting blood glucose			
ESR/CRP			
<b>Immunoglobulins:</b>			
IgG			
IgM			
IgA			
Other tests			

Other tests			
Other tests			

Serum Protein Electrophoresis?

**No**

**Yes**

**IF YES:**

☐

**Normal**

☐

**Monoclonal**

☐

**Polyclonal**

**18. Ethnic Group:** Choose ONE section from A to E in discussion with the patient, and then tick the appropriate box to indicate the patient's cultural background.

**a. White**

British

☐

Irish

☐

Any other White background

☐

(Please specify): \_\_\_\_\_

**b. Mixed**

White and Black Caribbean

☐

White and Black African

☐

White and Asian

☐

Any other Mixed background

☐

(Please specify): \_\_\_\_\_

**c. Asian or Asian British**

Indian

☐

Pakistani

☐

Bangladeshi

☐

Any other Asian background

☐

(Please specify): \_\_\_\_\_

**d. Black or Black British**

Caribbean

☐

African

☐

Any other Black background

☐

(Please specify): \_\_\_\_\_

**e. Chinese or other ethnic group**

Chinese

☐

Any other background

☐

(Please specify): \_\_\_\_\_

***This form should be accompanied by the following pre-therapy completed forms***

**BILAG 2004 index**

☐

**SLICC damage index**

☐

**SLEDAI 2K**

☐

**Thank you for completing this questionnaire – we will never ask this many questions again!**  
**Please enter the information into the BILAG BR electronic system.**