ID

For office use only

BSR Biologics Register – Rheumatoid Arthritis
Clinical Baseline Form

Please complete the following PATIENT information

Gender: Male ☐ Female ☐

Date of birth: D D M M Y Y Y Y

Hospital Reg. No:

NHS No:

Consultant Rheumatologist:

Name of Hospital:

Preferred clinical contact email address:

Form completion date (today's date): D D M M Y Y Y Y

Title: Mr / Mrs / Miss / Ms

Surname:

Forename/s:

Address:

Postcode:

Telephone Number:

1. Does the patient have **Rheumatoid Arthritis**? ☐ Yes ☐ No

If **NO**, can you specify the other diagnosis? ☐

1a. Does the patient have **ACPA (anti-CCP) positive RA?** ☐ Yes ☐ No ☐ Don't Know

2a. What was the year of diagnosis? ☐

2b. What year was this patient first seen by a rheumatologist? ☐

3. ACR Criteria (please indicate which of the following apply to the patient):

Yes	No	Don't know	
☐	☐	☐	Morning stiffness >1 hour (ever)
☐	☐	☐	Arthritis or deformity/damage of three or more joint areas (PIP, MCP, wrist, elbow, knee, ankle, MTP) (now)
☐	☐	☐	Arthritis/deformity of hand/joint (now)
☐	☐	☐	Symmetry
☐	☐	☐	Nodules (ever)
☐	☐	☐	Rheumatoid factor positive (≥ 1/40) (ever)
☐	☐	☐	Erosions on hand or feet x-ray

4. Systemic features: Has the patient <u>ever</u> had any of the following?

Yes	No	Don't know	
☐	☐	☐	Sicca syndrome
☐	☐	☐	Serosal involvement (pleurisy/pericarditis)
☐	☐	☐	Eye involvement
☐	☐	☐	Systemic vasculitis
☐	☐	☐	Nailfold vasculitis
☐	☐	☐	Pulmonary fibrosis
☐	☐	☐	Other (please specify)

5. Joint replacements/surgery: Has the patient <u>ever</u> had any of the following?

	Unilateral	Bilateral
Total knee replacement		
Total hip replacement		
Total shoulder replacement		
Total elbow replacement		
Wrist/hand/ankle/foot surgery		
Neck surgery		

6. Please indicate the current disease activity (i.e. at the time the patient started the new drug)

28 tender joint count

28 swollen joint count

ESR **AND / OR** CRP

Patient global assessment (VAS) mm

(Out of 100)

Total DAS score (if known):

Date DAS28 taken:

____/_____/_____

DD MM YYYY

For patients switching from an **originator** to a **biosimilar** of the **same** product:- **If DAS 28 is unavailable**, was the patient in **low disease activity/remission** at the time of the switch to the biosimilar, based on the information available?

YES ☐ NO ☐

7. Drug therapy: Please list all the patient's current treatment, for any indication

8. New Biologic/Targeted Therapy (please use trade name)**:**

Which drug has the patient started?								
	Enbrel ☐	**Cimzia** ☐	**Inflectra** ☐	**Other*** ☐
	Remicade ☐	**RoActemra** ☐	**Flixabi** ☐	**If other, please specify trade name:**
	Humira ☐	**Remsima** ☐	**Benepali** ☐	

**Please visit our website at www.bsrbr.org for the most up to date list of eligible therapies.*

Please indicate the date of first therapy dose: D D M M Y Y Y Y

Please also indicate the average **dose and unit**: _____ Frequency: _____

Is this delivered intravenously or subcutaneously? ☐ IV ☐ SC

Please provide the product batch number of the first dose _____ Tick if unknown ☐

Is this the patient's first exposure to a biologic/targeted therapy? Yes ☐ No ☐ **If No, please give details below**

	Biologic therapy	**DAS28 prior to starting**	**Start date**	**Stop date**	**Reason for stopping**
1					
2					
3					
4					

Is the patient switching from an **originator** e.g. Remicade directly to a **biosimilar** of the **same** product, i.e. Inflectra or Remsima? Yes ☐ No ☐

If **yes**, please provide the reason for this switch and any comments below:

Comments:

☐ Clinical indication
☐ Patient choice
☐ Cost factors
☐ Other

Is the patient still on biologic/targeted therapy? Yes ☐ No ☐ **If NO, please give details on a separate sheet**

9. Is the patient currently receiving DMARD therapy? Yes ☐ No ☐

If **Yes**, please indicate which DMARD(s) and current dose.

DMARD Started (please tick)		mg	Frequency	Date Started D D M M Y Y
Methotrexate				
Azathioprine				
Cyclophosphamide				
Cyclosporine				
Leflunomide				
Other **:**				

10. Previous second-line drug therapy:

Has the patient EVER had any of the following drugs?

	Yes	No	Don't know
IM Gold			
Auranofin			
Penicillamine			
Sulphasalazine			
Chlor/HCQ			
Steroids			

→ If currently receiving steroids, please indicate dose: ☐

And route: ☐ IV ☐ SC ☐ Oral

We would now like to know more details about certain drugs:

	Yes	No	Don't know	1st Course Date started: Month	1st Course Date started: Year	1st Course Date stopped: Month	1st Course Date stopped: Year	2nd Course Date started: Month	2nd Course Date started: Year	2nd Course Date stopped: Month	2nd Course Date stopped: Year
Methotrexate											
Azathioprine											
Cyclophosphamide											
Cyclosporine											
Leflunomide											
Other, please specify											

If patient has started or stopped the same drug more than twice please give details on an additional sheet
(Do not include stopping a drug for less than three months)

11. Co-morbidity:

Has the patient <u>ever</u> had (i.e. required treatment for) any of the following illnesses? Please tick all that apply

	Yes	No	Don't know	Year of onset			
High blood pressure							
Angina							
Heart attack							
Stroke							
Epilepsy							
Asthma							
Chronic bronchitis/emphysema (COPD)							
Peptic ulcer							
Liver disease							
Renal disease							
TB							
Demyelination							
Diabetes*							
Hyperthyroidism							
Depression							
Cancer‡							

Other co-morbidity not listed _____

_____

_____

‡If the patient has (or has ever had) cancer please specify date of diagnosis and site(s):

*If the patient is diabetic is (s)he:

Insulin dependent ☐ Tablet controlled ☐ Diet controlled ☐

12. Smoking status: Is the patient a:

☐ Current smoker ☐ Ex-smoker ☐ Never-smoked

13. Blood pressure: what is the patient's <u>current</u> (i.e. at the time that the biologic agent was started) blood pressure?

Systolic ☐☐☐ mm

Diastolic ☐☐☐ mm

14. Height and weight: what is the patient's <u>current</u> (i.e. at the time that the biologic agent was started) height and weight?

Weight ☐☐☐ kg

Height ☐☐☐ cm

15. Did the patient have a chest x-ray prior to starting the new therapy?

Yes ☐

No ☐

16. Has the patient had a QuantiFERON, ELISPOT (or other Gamma interferon based assays for TB) test?

Yes ☐

No ☐

Date/Details:

17. Has the patient received the Herpes zoster vaccine?

☐ Yes ☐ Date ☐ No ☐ Don't know

Thank you for completing this form!

This form should be accompanied by the following <u>pre-biologic/targeted therapy</u> patient-completed forms:

HAQ ☐

EQ-5D ☐

Please return to:

BSRBR-RA
Arthritis Research UK Centre for Epidemiology
Unit 4 Rutherford House
Manchester Science Park
40 Pencroft Way
Manchester
M15 6SZ