MANCHESTER 1824
The University of Manchester

British Society for Rheumatology
Rheumatoid Arthritis Register

Consultant:

Consultant ID:

ID: Follow-up ☐

Clinical Follow-up Form – Version 11.3: 17/07/2017

Study ID: HRN:
Patient Initials: Gender: «Gender»
Patient Date of Birth: «DOB»
NHS Number: «NHS»

If you are unsure which patient the study number refers to please call the study offices on 0161 275 1652/7390

PLEASE INFORM US IF THIS PARTICIPANT CHANGES THEIR ADDRESS.
Please provide the following missing data for our records:
«request»

Section 1: BIOLOGIC/TARGETED THERAPY

On --/--/---- your patient was on no drug.

Since that date, have there been any changes to the patient's biologic/targeted therapy? ☐ Yes ☐ No
If yes, please record all changes below (continue on separate sheet if necessary)

Drug Details: TRADE NAME, Dose/unit, Route (IV/SC) and Batch number.	**Date started** (DD/MM/YY)	**Date of final dose** (DD/MM/YY)	If this is a drug **discontinuation** list reason here (codes below)	If this patient is switching to a **new biosimilar**, list reason here (codes below)	If this is a patient starting a new biologic or targeted therapy, please indicate the **DAS28 at the time of the switch**, and the **date taken**	If **DAS 28 unavailable** was the patient in low disease activity at **time of switch? please circle**
					Score: Date:	**Y / N**
					Score: Date:	**Y / N**
					Score: Date:	**Y / N**
					Score: Date:	**Y / N**

Discontinuation Code: 1. Inefficacy, 2. Remission, 3. Adverse Events *(please enter details in the adverse events section)*
4. Other – please give details here:

Switch to biosimilar Code: 1. Clinical Indication, 2. Patient Choice, 3. Cost Factors, 4. Other – please give details:

If the patient is newly starting Cimzia, Actemra/RoActemra, or a biosimilar (or other targeted therapy), are they being re-registered with the BSRBR-RA? (Full list of eligible drugs available at www.bsrbr.org)

☐ Yes ☐ No

Re-registrations are included in the UKCRN accrual uploads

RE-REGISTRATION CHECKLIST: Please include the following:

1. Re-consent the patient & signed consent form enclosed ☐
2. Indication of recent disease activity (e.g. DAS28) ☐
3. Recent HAQ and EQ-5D enclosed ☐
4. List of current medications (on separate sheet) ☐

***IV/SC FORMULATION: Has the patient received IV or SC forms of biologic/targeted therapy? If the patient has switched between routes of the same drug please provide details in the table below and indicate date of switch.**

Biologic/Targeted Therapy Trade Name	**Date of Switch**	**Direction of switch (IV to SC or SC to IV)**

For MabThera & rituximab biosimilar patients only: ☐ RA Flare ☐ Scheduled Infusion

→ If the patient has been re-treated with MabThera/a rituximab biosimilar please indicate why: ☐ Other: ----------

→ Have the immunoglobulin levels been measured? ☐ **No** ☐ **Yes → IgG:** _____ **IgM:** _____
IgA: _____ **Date of result:** _____

Please list the dates and doses of **Infusions received** since --/--/----. Please give **drug trade name** and **date/dose** of each infusion:

Section2: DMARD THERAPY

On --/--/---- your patient was on .

Since that date, have there been any changes to the patient's DMARD therapy? ☐ Yes ☐ No
If yes, please record all changes below **(continue on separate sheet if necessary)**

Drug name	Dose and Unit	Date started (dd/mm/yyyy)	Date of final dose (dd/mm/yyyy)	If this is a drug discontinuation, list **reason** here (codes same as section 1)

Section 3: STEROIDS

Since --/--/---- has your patient had any steroids? Yes ☐ No ☐

i) IM/IV/joint injection? Yes ☐ No ☐ **ii) oral steroids?** Yes ☐ No ☐

Section 4: ADVERSE EVENTS AND NEW ILLNESSES

Since 03/04/2013 has your patient experienced any new illness or adverse events (whether or not related to any medication)?
Yes ☐ No ☐ **If Yes, please provide details below and continue on a separate sheet if necessary**

Adverse Event/ New Illness #1: _____ **Date:** _____

→ Was the patient on a biologic/targeted therapy at the time of the new illness? Yes ☐ No ☐

→ Was the event **SERIOUS**? Yes ☐ No ☐ (If yes, please circle reason(s) below)

Event was serious due to resulting in: death/ hospitalisation/ IV antibiotics/ significant loss of function or disability/ congenital malformation/ was in any other way life threatening?

Please provide all event details available:

_____
_____
_____
_____

- Did this event lead to biologic/targeted therapy discontinuation?

☐ Yes -permanently ☐ Yes – temporarily → please provide discontinuation date and re-start date if known:
☐ No ☐ Don't Know

- Do you believe there is a possibility this event was related to the biologic/targeted therapy used to treat RA? Yes ☐ No ☐ Don't know ☐
- If yes, which biologic/targeted therapy (trade name and batch number if available)? _____

Adverse Event/ New Illness #2: _____ **Date:** _____

→ Was the patient on a biologic/targeted therapy at the time of the new illness? Yes ☐ No ☐

→ Was the event **SERIOUS**? Yes ☐ No ☐ (If yes, please circle reason(s) below)

Event was serious due to resulting in: death/ hospitalisation/ IV antibiotics/ significant loss of function or disability/ congenital malformation/ was in any other way life threatening?

Please provide all event details available:

_____
_____
_____
_____

- Did this event lead to biologic/targeted therapy discontinuation?

☐ Yes -permanently ☐ Yes – temporarily → please provide discontinuation date and re-start date if known:
☐ No ☐ Don't Know

- Do you believe there is a possibility this event was related to the biologic/targeted therapy used to treat RA? Yes ☐ No ☐ Don't know ☐
- If yes, which biologic/targeted therapy (trade name and batch number if available)? _____

Adverse Event/ New Illness #3: _____ **Date:** _____

→ Was the patient on a biologic/targeted therapy at the time of the new illness? **Yes** ☐ **No** ☐

→ Was the event **SERIOUS**? **Yes** ☐ **No** ☐ (If yes, please circle reason(s) below)

Event was serious due to resulting in: death/ hospitalisation/ IV antibiotics/ significant loss of function or disability/ congenital malformation/ was in any other way life threatening?

Please provide all event details available:

_____
_____
_____
_____

- Did this event lead to biologic/targeted therapy discontinuation?

☐ Yes -permanently ☐ Yes – temporarily → please provide discontinuation date and re-start date if known:

☐ No ☐ Don't Know

- Do you believe there is a possibility this event was related to the biologic/targeted therapy used to treat RA? **Yes** ☐ **No** ☐ **Don't know** ☐

- If yes, which biologic/targeted therapy (trade name and batch number if available)? _____

If your patient has experienced more than three adverse events/ new illnesses, please include details as above on a separate sheet.

✶✶EVENTS OF SPECIAL INTEREST✶✶

IF ANY OF THE SERIOUS ADVERSE EVENTS YOU HAVE LISTED INCLUDE ONE OF THE FOLLOWING PLEASE COMPLETE AN 'EVENT OF SPECIAL INTEREST FORM'

- Aplastic anaemia, Pancytopaenia, Serious Neutropenia
- Serious Congestive heart failure
- Cerebrovascular accident (CVA)
- Demyelination/Optic neuritis
- Lymphoproliferative Malignancy
- Malignancy including skin cancer/Bowen's disease
- Myocardial Infarction/Serious Acute Coronary Syndrome
- Pregnancy
- Pulmonary Embolism
- Serious Infection
- Tuberculosis
- Serious Lupus/Lupus-like illness
- Hepatitis B Reactivation
- Serious Haemorrhage
- Serious skin reaction (e.g. Stevens Johnson syndrome, erythema multiforme, toxic epidermal necrosis)
- Serious lower GI ulcer/bleed/perforation
- Serious hepatic dysfunction/failure
- Serious hypersensitivity reaction

The Event of Special Interest (ESI) forms can be downloaded from our website (address below), or call the office on 0161 275 1652 and we can email or post one to you. Please attach the ESI form to this follow-up form when returning to the study team. Thank you!

Most recent DAS-28

28 tender joint count……..

28 swollen joint count……..

ESR ……

CRP……..

Patient Global Assessment……..

Total DAS if known:

Patient Vital Status

☐ **Alive**

☐ **Died**

Date of Death:

Death Details

If your patient has died, please provide the following:

1. Was the patient receiving biologic therapy at time of death? Y / N
2. If **Yes**, which drug?_____
3. Date of first dose: _____
4. Date of last dose: _____
5. If **No,** what was the last biologic received? _____
6. What was the date of the final dose? _____

Date of DAS-28 Score …../……/……

Patient's current weight:

Name of Person Completing Form:_____
Contact Telephone Number/Email;_____
Date Form Completed: _____

Thank you for taking the time to fill in this questionnaire. Please return it now (in the pre-paid envelope provided).

www.bsrbr.org

BSRBR-RA Office Contact details: Unit 4 Rutherford House, 40 Pencroft Way, Manchester. M15 6SZ / 0161 275 1652/7390 / biologics.register@manchester.ac.uk