

**BSRBR-RA Event of Special Interest (ESI) Report
SERIOUS LUPUS OR LUPUS-LIKE ILLNESS**

Study ID: HRN: Patient Initials:	Gender: Date of Birth: NHS Number:
Event Date:	Biologic/biosimilar at time of event: Product Batch Number:

Event Details

Diagnosis:

Drug induced lupus Exacerbation of SLE Unmasking of SLE
Other (details: _____)

Symptoms Onset over:

..... Days / Weeks / Months

Which clinical features were present? (If yes give evidence e.g. infiltrates on chest x-ray)

Constitutional symptoms Yes No Skin Yes No
Serositis Yes No Renal involvement Yes No
Neurological involvement Yes No Immunological abnormality Yes No
Worsening arthritis Yes No Please give current DAS28: _____
Please record result of ANA, ENA, DNA and complement if done, including date/s:

Drug Details

Has biologic/biosimilar been stopped due to event? Yes No Date stopped: _____

Has the condition resolved on stopping biologic/biosimilar? Yes No

Was the patient taking any other drugs that have been associated with drug induced lupus?

E.g. sulphasalazine, penacillamine Yes No (If Yes please state below with stop date)

Has other medication been stopped? Yes No (If Yes please state below with stop date)

Did this event require the initiation of or increased dose of corticosteroid? Yes No

Do you believe there is a possibility that this adverse event was related to the biologic/biosimilar drug used to treat RA? Yes No Unknown

If **Yes** please confirm which drug: _____

What was the outcome of the event?

Resolved Not Resolved Resolved with sequelae Fatal

Form completed:
By: _____
On: ____/____/____

Return ESI/s to: BSRBR-RA. The University of Manchester,
Unit 4 Rutherford House, 40 Pencroft Way, Manchester Science Park
Manchester, M15 6SZ. You can also fax these to: 0161 2751640