MANCHESTER 1824
The University of Manchester
British Society for Rheumatology
Rheumatoid Arthritis Register

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 - Please add any additional information & diagnosis

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. biologics.register@manchester.ac.uk