



**BSRBR-RA Event of Special Interest (ESI) Report
SERIOUS HAEMORRHAGE**

Study ID:
HRN:
Patient Initials:

Gender:
Date of Birth:
NHS Number:

Event Date:

Biologic/biosimilar at time of event:
Product Batch Number:

Please note Serious Adverse Events are those resulting in: Death, Hospitalisation, IV Antibiotics, Significant loss of function or immediately life threatening.

Event Details:

Medication at time of event:

Was the event pregnancy/ delivery related? YES NO (If yes complete pregnancy ESI also)

What was the patient's Lowest Hb recorded:

Does the patient have a known bleeding disorder? YES NO UNKNOWN

If yes please provide details:

Did the event result in?

Hospitalisation YES/ NO Length of hospitalisation:

Surgical Procedure YES/ NO Procedure:

Transfusion YES/ NO Details:

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