

## BSRBR-RA Event of Special Interest (ESI) SERIOUS INFECTION

**Study ID:**  
**HRN:**  
**Patient Initials:**

**Gender:**  
**Date of Birth:**  
**NHS Number:**

**Event Date:**

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

**Event**

Site of infection:

Were microbiological/serological tests carried out?    YES / NO / DON'T KNOW (Circle)  
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If yes, specify micro-organism / serological result:  
(Please state if nil grown)

Medication at time of infection:

At the **TIME OF INFECTION** did the patient have?

Indwelling catheter                     YES     NO     DON'T KNOW

Intravenous access (e.g., Hickman's Line)     YES     NO     DON'T KNOW

Any wounds or ulcers                     YES     NO     DON'T KNOW

**At the TIME OF INFECTION what was the patient's:**

White cell count: \_\_\_\_\_

Neutrophil count: \_\_\_\_\_

Lymphocyte count: \_\_\_\_\_

**PRIOR TO THE INFECTION what was the patient's:** (TAKEN ON: \_\_\_\_/\_\_\_\_/\_\_\_\_)

White cell count: \_\_\_\_\_

Neutrophil count: \_\_\_\_\_

Lymphocyte count: \_\_\_\_\_

Has the patient ever had Felty's?                     YES     NO     DON'T KNOW

Has the patient ever had a splenectomy?                     YES     NO     DON'T KNOW

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,  
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Manchester, M15 6SZ. biologics.register@manchester.ac.uk