BSRBR-RA Event of Special Interest (ESI)
TUBERCULOSIS

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 annotate with any additional information)

Site of infection:

Diagnosis based on:

Clinical signs and symptoms ☐ Chest X-Ray / CT Scan ☐

☐ PCR **If yes, please specify sample:** _____

☐ Acid fast bacilli **If yes, please specify sample:** _____

☐ Histology **If yes, please specify sample:** _____

Diagnosis confirmed by CULTURE? YES / NO (please circle)

If yes, please specify sample: _____

Pre-treatment screening measures performed on patient:

☐ PPD results ☐ mm

☐ IGRA Result (Quantiferon) ☐ Positive Indeterminate ☐ Negative ☐

☐ Chest X-Ray → Did this indicate latent TB? ☐ Yes ☐ No

Please note any **relevant** family history: _____

Country of birth: _____ No of years lived in UK: _____

Has the patient received TB prophylaxis? ☐ YES ☐ NO ☐ UNKNOWN

If yes please provide start date: _____ and end date: _____

Please indicate which medication:

Medication prescribed to treat **active** TB:

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