



# BSRBR-RA Event of Special Interest (ESI) TUBERCULOSIS

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

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. You can also fax these to: 0161 2751640