

BSRBR-RA Event of Special Interest (ESI) MALIGNANCY

Study ID: _____
HRN: _____
Patient Initials: _____

Gender: _____
Date of Birth: _____
NHS Number: _____

Event Date: _____

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

Event Details

Details of Malignancy (including diagnosis, location & cell type if available)

Date of diagnosis: ____/____/____
(Please provide any histopathology/radiology reports)

Did the patient have:

Surgery	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>	DON'T KNOW	<input type="checkbox"/>
Radiotherapy	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>	DON'T KNOW	<input type="checkbox"/>
Chemotherapy	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>	DON'T KNOW	<input type="checkbox"/>

Other treatment: _____

Was the neoplasm:

Benign	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>	DON'T KNOW
Malignant	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>	DON'T KNOW
Carcinoma in situ	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>	DON'T KNOW
A Metastasis	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>	DON'T KNOW

Did the malignancy have associated metastases? YES NO DON'T KNOW

Please provide name & hospital of doctor treating the malignancy if available:

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