

BSRBR-RA Event of Special Interest (ESI) CVA

Study ID: HRN: Patient Initials:	Gender: Date of Birth: NHS Number:
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Event Date:	Biologic/biosimilar at time of event: Product Batch Number:
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Event Details (please annotate with any additional information)

Was the stroke haemorrhagic	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> DON'T KNOW
Or ischaemic	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> DON'T KNOW

Was the patient thrombolised?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> DON'T KNOW
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Does the patient have atrial fibrillation?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> DON'T KNOW
Or paroxysmal atrial fibrillation?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> DON'T KNOW

Was a CT/MRI done?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> DON'T KNOW	(If yes, please attach report)
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Did signs/symptoms fully resolve?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> DON'T KNOW
If so, did they resolve within:	<input type="checkbox"/> 24 hours	<input type="checkbox"/> 1 week	<input type="checkbox"/> More than one week

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
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