



BSRBR-RA Event of Special Interest (ESI) Report Serious Rheumatic Therapy Hypersensitivity Reaction

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

Was this reaction associated with an **INFUSION** or **INJECTION** (please circle)

Event Details - Please describe any **signs** OR **symptoms** of the hypersensitivity reaction:

Has this patient ever developed hypersensitivity to biologics before? Yes No
 If **Yes**, please provide details:

How long after the start of administration of the infusion/injection did the event occur?
 hours minutes or Days.

Is the hypersensitivity reaction considered systemic ?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Don't Know	<input type="checkbox"/> N/A
Is the hypersensitivity reaction considered local ?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Don't Know	<input type="checkbox"/> N/A
Did the reaction occur at injection site ?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Don't Know	<input type="checkbox"/> N/A
If Yes , was it at the most recent injection site?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Don't Know	<input type="checkbox"/> N/A

Was the infusion/injection stopped prematurely? Yes No Don't Know

Was the reaction fatal or life threatening? Yes No

Was the patient admitted to hospital overnight as a result of the reaction? Yes No

Was additional medication administered before/during or after infusion/injection: e.g. steroids, antihistamines, epinephrine, etc?

Before:

During:

After:

Which laboratory tests (if any) were done?
 Please provide results if applicable

Has this reaction resulted in a permanent discontinuation of this biologic/biosimilar drug?
 Yes No

Please provide start and discontinuation dates for this drug:

What was the outcome? Not Resolved 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
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