MANCHESTER 1824
The University of Manchester

British Society for Rheumatology
Rheumatoid Arthritis Register

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?**	☐ Yes	☐ No	☐ Don't Know	☐ N/A
Is the hypersensitivity reaction considered **local?**	☐ Yes	☐ No	☐ Don't Know	☐ N/A
Did the reaction occur at **injection site?**	☐ Yes	☐ No	☐ Don't Know	☐ N/A
If **Yes**, was it at the **most recent** injection site?	☐ Yes	☐ No	☐ Don't Know	☐ 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. biologics.register@manchester.ac.uk