

**BSRBR-RA Event of Special Interest (ESI) Report  
SERIOUS SKIN REACTION**

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

**Event Details** (please annotate with any additional information & attach any skin histology reports available)

**What was the diagnosis?** (Please circle)

Stevens Johnson Syndrome / Toxic epidermal necrolysis / DRESS syndrome /

Drug Induced Hypersensitivity Syndrome / Other (please state) \_\_\_\_\_

**Diagnosis made/confirmed by dermatology?** YES / NO / DON'T KNOW

**Was an infective cause identified?** (E.g. herpes simplex / mycoplasma) YES / NO / DON'T KNOW

**If yes, please state:** \_\_\_\_\_

**Extent of skin involved** (% body surface area e.g. <10%, 10-30%, >30%) \_\_\_\_\_%

**Involvement of mucous membranes?** YES / NO / DON'T KNOW

**Did the patient have a fever?** (If yes, please give highest recorded temperature) YES / NO / DON'T KNOW \_\_

**Blood eosinophilia?** YES / NO / DON'T KNOW

**Organ involvement?** (Circle all that apply) Liver / Kidney / Heart / Lung / Other (please list) \_\_\_\_\_

**Drug detail**

**Can you confirm the date of the patient's last biologic/biosimilar dose, prior to this event?**

Drug name: \_\_\_\_\_ Date of last dose (prior to event): \_\_\_/\_\_\_/\_\_\_

**Is the patient's biologic/biosimilar therapy the most likely cause of the reaction?** YES / NO / DON'T KNOW

**What medications was the patient receiving at the time of onset of the skin reaction?**

(Please include any transient prescriptions in the preceding month such as antibiotics)

**Prior to the event was the patient receiving any of the following:** (circle all that apply)

NSAIDS / Anti-psychotics / Anti-epileptics / Sulphonamides / Antibiotics / Allopurinol / Dapsone

**Has the patient had a serious skin reaction to any other drug previously? (If so please give details)**

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