



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

Study ID:

HRN:

Patient Initials:

Gender:

Date of Birth:

NHS Number:

Event Date:

Biologic/biosimilar at time of event:

Product Batch Number:

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. biologics.register@manchester.ac.uk