



BILAG BR Event of Special Interest (ESI) APLASTIC ANÆMIA, PANCYTOPÆNIA / SERIOUS NEUTROPÆNIA

Patient Name:

Date of Birth:

PATIENT ID:

HRN:

Biologic at time of event:

Date of Event:

Product Batch Number:

(please tick here if unknown ☐)

Event Details (please annotate with any additional information)

What was the diagnosis?

Please provide the **lowest Hb value:** _____

lowest neutrophil value: _____

lowest platelet value: _____

- Did the patient have any cytopaenic history prior to starting therapy? ☐ YES ☐ NO
- Was a bone marrow aspiration / biopsy performed? ☐ YES ☐ NO

(If yes, please send a copy of the results)

Please indicate **concomitant medications** taken:

Were there any complications as a direct result of cytopaenia? (E.g. infection or bleeding)

What was the outcome?

☐

Resolved

☐

Not Resolved

☐

Resolved with sequelae

☐

Fatal

Has a yellow card been submitted?

☐

YES

☐

NO

☐

UNKNOWN

Form completed

By: _____

On: ____/____/____

Return to: BILAG BR, The University of Manchester, Rutherford House, 40 Pencroft Way, Manchester. M15 6SZ, or fax to 0161 275 1640.

Thank you for your help!



BILAG BR Event of Special Interest (ESI) Report CONGESTIVE HEART FAILURE

Patient Name:	Date of Birth:
PATIENT ID:	HRN:
Biologic at time of event: Product Batch Number: _____ (please tick here if unknown <input type="checkbox"/>)	Date of Event:

Event Details (please annotate with any additional information)

What was the diagnosis?

Is this event: ☐ New onset ☐ Worsening ☐ Unknown

Cardiac function investigation performed? ☐ YES ☐ NO If yes, please provide details

• LV ejection fraction: ____%

• BNP Level: ____Units

Please attach a copy of ECHO performed closest to the date of the event if possible

Cardiovascular risk factors:

→ Diabetes	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> DON'T KNOW
→ Hypertension	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> DON'T KNOW
→ Hypercholesterolaemia	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> DON'T KNOW
→ Positive family history	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> DON'T KNOW

What was the outcome? ☐ Resolved ☐ Not Resolved
☐ Resolved with sequelae ☐ Fatal

Has a yellow card been submitted? ☐ YES ☐ NO ☐ UNKNOWN

Form completed

By: _____

On: ____/____/____

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House, 40 Pencroft Way, Manchester. M15 6SZ,
or fax to 0161 275 1640. **Thank you for your help!**



BILAG BR Event of Special Interest (ESI) Report CVA

Patient Name:	Date of Birth:
PATIENT ID:	HRN:
Biologic at time of event: Product Batch Number: (please tick here if unknown <input type="checkbox"/>)	Date of Event:

Event Details (please annotate with any additional information)

Was the stroke haemorrhagic ☐ YES ☐ NO ☐ DON'T KNOW
 Or ischaemic ☐ YES ☐ NO ☐ DON'T KNOW

Was the patient thrombolised? ☐ YES ☐ NO ☐ DON'T KNOW

Does the patient have atrial fibrillation? ☐ YES ☐ NO ☐ DON'T KNOW
 Or paroxysmal atrial fibrillation? ☐ YES ☐ NO ☐ DON'T KNOW

Was a CT/MRI done? ☐ YES ☐ NO ☐ DON'T KNOW
 (If yes, please attach report)

Did signs/symptoms fully resolve? ☐ YES ☐ NO ☐ DON'T KNOW
 If so, did they resolve within: ☐ 24 hours ☐ 1 week ☐ More than one week

What was the outcome? ☐ Resolved ☐ Not Resolved
☐ Resolved with sequelae ☐ Fatal
 Has a yellow card been submitted? ☐ YES ☐ NO ☐ UNKNOWN

Form completed
 By: _____
 On: ____/____/____

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Thank you for your help!



Patient Name:	Date of Birth:
PATIENT ID:	HRN:
(please tick here if unknown <input type="checkbox"/>)	Date of Event:

Event Details (please annotate with any additional information)

What was the diagnosis?

What was the pattern of the disease?

☐ Eye involvement

☐ Spinal involvement

☐ Cranial involvement

Is this event: ☐ a new onset or ☐ a relapse?

Was this confirmed by a neurologist? ☐ YES ☐ NO

• Was an **MRI** conducted? ☐ YES ☐ NO (if yes please provide copies of report)

• Was **CSF** examined? ☐ YES → were oligoclonal bands present? **YES / NO**
☐ NO

• Visual evoked potentials? ☐ YES ☐ NO

• Positive history of neurological disorders?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	Type: _____
• Positive family history of neurological disorders?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	Type: _____

What was the outcome? ☐ Resolved ☐ Not Resolved
☐ Resolved with sequelae ☐ Fatal

Has a yellow card been submitted? ☐ YES ☐ NO ☐ UNKNOWN

Form completed
By: _____
On: ____/____/____

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BILAG BR Event of Special Interest (ESI) Report Rituximab Infusion/ Immunologic Reaction

Patient Name:	Date of Birth:
PATIENT ID:	HRN:
Biologic at time of event: Product Batch Number: _____ (please tick here if unknown <input type="checkbox"/>)	Date of Event:

Event Details (Please annotate any additional information/describe in detail the **signs** and **symptoms** involved in the reaction)

Did any of the first signs/symptoms occur within **24hrs** of the infusion: ☐ YES ☐ NO
 If **yes**, please describe:

How long after the infusion did the event occur? ☐ Within **24hrs** or ☐ **Days** (please state)

Was the infusion **stopped** prematurely? YES ☐ NO ☐
 Was the reaction **fatal/ life threatening**? YES ☐ NO ☐
 Was the patient **admitted** to hospital overnight as a result of the reaction? YES ☐ NO ☐

What additional medication was administered?

As premedication before/during infusion:
 (i.e. steroids, anti-histamines)

During/after the event:

Other additional medication:

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

Is any further treatment with **Rituximab** considered to be contraindicated?
☐ YES ☐ NO

What was the outcome? ☐ Resolved ☐ Not Resolved
☐ Resolved with sequelae ☐ Fatal

Has a yellow card been submitted? ☐ YES ☐ NO ☐ UNKNOWN

Form completed

by: _____
 on: ____/____/____

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BILAG BR Event of Special Interest (ESI) Report LYMPHOPROLIFERATIVE MALIGNANCY

Patient Name:	Date of Birth:
PATIENT ID:	HRN:
Biologic at time of event: Product Batch Number: (please tick here if unknown <input type="checkbox"/>)	Date of Event:

Event Details (please annotate with any additional information)

What was the diagnosis? (Please include site)

Histopathological classification & Staging/ Radiology: (If known, please enclose a copy of the results)

Treatment Regime:

Withdrawal of MTX, no other treatment given ☐

Withdrawal of Anti TNF, no other treatment given ☐

☐ Surgery

☐ Chemo regime

☐ Rituximab

☐ Radiotherapy

Tissue EBV Status:

☐ Positive

☐ Negative

☐ Unknown

Past history of Sjögren's disease?

☐ YES

☐ NO

☐ DON'T KNOW

Please provide name & hospital of doctor treating the malignancy if available:

Positive family history of cancer?

☐ YES

☐ NO

☐ DON'T KNOW

What was the outcome?

☐ Resolved

☐ Not Resolved

☐ Resolved with sequelae

☐ Fatal

Has a yellow card been submitted?

☐ YES

☐ NO

☐ UNKNOWN

Form completed

By: _____

On: ____/____/____

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BILAG BR Event of Special Interest (ESI) Report MALIGNANCY

Patient Name:	Date of Birth:
PATIENT ID:	HRN:
Biologic at time of event: Product Batch Number: _____ (please tick here if unknown <input type="checkbox"/>)	Date of Event:

Event Details

Details of Malignancy (including diagnosis, location & cell type if available)

Date of diagnosis: ____/____/____
(Please provide any histopathology/radiology reports)

Did the patient have:

Surgery	YES <input type="checkbox"/>	NO <input type="checkbox"/>	DON'T KNOW <input type="checkbox"/>
Radiotherapy	YES <input type="checkbox"/>	NO <input type="checkbox"/>	DON'T KNOW <input type="checkbox"/>
Chemotherapy	YES <input type="checkbox"/>	NO <input type="checkbox"/>	DON'T KNOW <input type="checkbox"/>

Other treatment: _____

Was the neoplasm:

Benign	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> DON'T KNOW
Malignant	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> DON'T KNOW
Carcinoma in situ	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> DON'T KNOW
A Metastasis	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> DON'T KNOW

Did the malignancy have associated metastases? ☐ YES ☐ NO
☐ DON'T KNOW

Please provide name & hospital of doctor treating the malignancy if available:

What was the outcome? ☐ Resolved ☐ Not Resolved
☐ Resolved with sequelae ☐ Fatal

Has a yellow card been submitted? ☐ YES ☐ NO ☐ UNKNOWN

Form completed

By: _____

On: ____/____/____

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BILAG BR Event of Special Interest (ESI) Report MI / ACUTE CORONARY SYNDROME

Patient Name:	Date of Birth:
PATIENT ID:	HRN:
Biologic at time of event:	
Product Batch Number: _____	Date of Event:
(please tick here if unknown <input type="checkbox"/>)	

Event Details (please annotate with any additional information)

Rise in cardiac markers? ☐ YES ☐ NO ☐ DON'T KNOW

Trop T/ Trop I Level: _____ (Highest level recorded)

Did the patient have ischaemic symptoms? ☐ YES ☐ NO ☐ DON'T KNOW

ECG findings → Were there any ischaemic changes ☐ YES ☐ NO ☐ DON'T KNOW

→ Were there any new Q waves ☐ YES ☐ NO ☐ DON'T KNOW

Was the patient thrombolysed? ☐ YES ☐ NO ☐ DON'T KNOW

Did they receive primary angioplasty on the same day as the event?

☐ YES ☐ NO ☐ DON'T KNOW

Did they have any other cardiac intervention? ☐ YES ☐ NO ☐ DON'T KNOW

If yes, please specify what & when:

Form completed

By: _____

On: ____/____/____

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Thank you for your help!



BILAG BR Event of Special Interest (ESI) Report PREGNANCY

Patient Name:	Date of Birth:
PATIENT ID:	HRN:
Last biologic therapy recorded:	Product Batch Number: (Please tick here if unknown <input type="checkbox"/>)

Pregnancy Details:

Please provide the following details regarding this event

CONCEPTION

Did the patient receive pre-conception counselling?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Were there any difficulties in conceiving?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Was patient receiving biologic therapy at the time of conception?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Was patient receiving DMARD therapy at the time of conception?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No

If yes, please provide details:

Approximate date of conception:

Please provide details of any previous pregnancies, including any complications, outcome and year?

GESTATION

Did the patient have any complications during pregnancy? ☐ Yes ☐ No

Details:

Date of event:

Was the patient hospitalised?

☐

Yes

☐

No

Did the patient experience any infections during pregnancy?

☐

Yes

☐

No

Details:

Date of event:

Was the patient hospitalised?

☐

Yes

☐

No

BILAG BR Event of Special Interest (ESI) Report PREGNANCY

If the patient has **rheumatoid arthritis**, did the disease remit during pregnancy? ☐ Yes ☐ No

Did the patient remain on biologic therapy throughout the pregnancy? ☐ Yes ☐ No

If not, did they discontinue in the ☐ first ☐ second or ☐ third trimester?

Did the patient remain on DMARD therapy throughout the pregnancy? ☐ Yes ☐ No

If not, did they discontinue in the ☐ first ☐ second or ☐ third trimester?

DELIVERY

What was the length of gestation?

Weeks

What was the date of delivery?

What was the method of delivery?

☐ Spontaneous vaginal

☐ Assisted vaginal

☐ Planned caesarian

☐ Emergency caesarian

Did the patient have any complications during labour and delivery? ☐ Yes ☐ No

If yes, please provide details:

Did the baby have any congenital abnormalities? ☐ Yes ☐ No

If yes, please provide details:

POSTPARTUM

Did the patient develop any postpartum complications? ☐ Yes ☐ No

If yes, please provide details:

Specifically, did the patient develop any postpartum infections? ☐ Yes ☐ No

If yes, please provide details:

Is the patient breastfeeding? ☐ Yes ☐ No

Did the infant develop any neonatal complications? ☐ Yes ☐ No

If yes, please provide details:

Form completed

By:

On: / /

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Thank you for your help!



BILAG BR Event of Special Interest (ESI) Report PULMONARY EMBOLISM

Patient Name:	Date of Birth:
PATIENT ID:	HRN:
Biologic at time of event: Product Batch Number: _____ (please tick here if unknown <input type="checkbox"/>)	Date of Event:

Event Details (please annotate with any additional information)

Diagnosis confirmed by:

- VQ Scan ☐ YES ☐ NO ☐ DON'T KNOW
- CTPA ☐ YES ☐ NO ☐ DON'T KNOW
- Other (Please specify) _____

Please enclose copies of scan reports wherever possible

Was a surgical procedure performed in the 8 weeks prior to the event?

☐ YES ☐ NO ☐ DON'T KNOW

If yes, please specify what: _____

Date performed: ____/____/____

What was the outcome of the event? ☐ FATAL ☐ RESOLVED

Has the patient had a previous PE/ DVT? ☐ YES ☐ NO ☐ DON'T KNOW

Form completed

By: _____
On: ____/____/____

Return to: BILAG BR, Arthritis Research UK Epidemiology Unit, The University of Manchester, Rutherford House, 40 Pencroft Way, Manchester. M15 6SZ, or fax to 0161 275 1640.
Thank you for your help!



BILAG BR Event of Special Interest (ESI) Report SERIOUS INFECTION

Patient Name:	Date of Birth:
PATIENT ID:	HRN:
Biologic at time of event: Product Batch Number: _____ (please tick here if unknown <input type="checkbox"/>)	Date of Event:

Event:

Site of infection:

Were microbiological/serological tests carried out? YES / NO / DON'T KNOW (Circle)

If yes, specify micro-organism / serological result: _____
(Please state if nil grown)

Medication at time of infection:

At the **TIME OF INFECTION** did the patient have?

Indwelling catheter	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>	DON'T KNOW
Intravenous access (e.g., Hickman's Line)	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>	DON'T KNOW
Any wounds or ulcers	<input type="checkbox"/>	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>	DON'T KNOW

At the TIME OF INFECTION what was the patient's:

White cell count: _____

Neutrophil count: _____

Lymphocyte count: _____

PRIOR TO THE INFECTION what was the patient's: (TAKEN ON: ____/____/____)

White cell count: _____

Neutrophil count: _____

Lymphocyte count: _____

Has the patient ever had Felty's? ☐ YES ☐ NO ☐ DON'T KNOW

Has the patient ever had a splenectomy? ☐ YES ☐ NO ☐ DON'T KNOW

What was the outcome? ☐ Resolved ☐ Not Resolved

☐ Resolved with sequelae ☐ Fatal

Has a yellow card been submitted? ☐ YES ☐ NO ☐ UNKNOWN

Form completed
By: _____
On: ____/____/____

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40 Pencroft Way, Manchester. M15 6SZ
or fax to 0161 275 1640.
Thank you for your help!



BILAG BR Event of Special Interest (ESI) Report TUBERCULOSIS

Patient Name:	Date of Birth:
PATIENT ID:	HRN:
Biologic at time of event: Product Batch Number: _____ (please tick here if unknown <input type="checkbox"/>)	Date of Event:

Event Details (please annotate with any additional information)

SITE OF INFECTION:

Diagnosis based on:

<input type="checkbox"/> Clinical signs and symptoms	<input type="checkbox"/> Chest X-Ray / CT Scan
<input type="checkbox"/> PCR	If yes, please specify sample: _____
<input type="checkbox"/> Acid fast bacilli	If yes, please specify sample: _____
<input type="checkbox"/> Histology	If yes, please specify sample: _____

Diagnosis confirmed by CULTURE? YES / NO (please circle)

If yes, please specify sample: _____

Pre-treatment screening measures performed on patient:

<input type="checkbox"/> PPD results	<input type="checkbox"/> mm	<input type="checkbox"/> IGRA Result (Quantiferon)	<input type="checkbox"/> Positive	<input type="checkbox"/> Indeterminate	<input type="checkbox"/> Negative
<input type="checkbox"/> Chest X-Ray →	Did this indicate latent TB?		<input type="checkbox"/> Yes	<input type="checkbox"/> No	

Please note any **relevant** family history: _____

Country of birth: _____ No of years lived in UK: _____

Has the patient received TB prophylaxis? ☐ YES ☐ NO ☐ UNKNOWN

If yes please provide start date: _____ and end date: _____

Please indicate which medication:

Medication prescribed to treat **active** TB:

Has a yellow card been submitted? ☐ YES ☐ NO ☐ DON'T KNOW

Form completed

By: _____

On: ____/____/____

Return to: BILAG BR, Arthritis Research UK Epidemiology Unit, The University of Manchester, Rutherford House, 40 Pencroft Way, Manchester. M15 6SZ, or fax to 0161 275 1640.

Thank you for your help!



BILAG BR Event of Special Interest (ESI) Report LUPUS OR LUPUS-LIKE ILLNESS

Patient Name:

Date of Birth:

PATIENT ID:

HRN:

Biologic at time of event:

Date of Event:

Product Batch Number:

(please tick here if unknown ☐)

Event Details - Please add any additional information & diagnosis

Diagnosis:

Drug induced lupus ☐

Unmasking of SLE ☐

Exacerbation of SLE ☐

Other ☐

Details: _____

Symptoms Onset over:

.....Days

.....Weeks

.....Months

Which clinical features were present? (Tick yes/no, if yes give evidence e.g. infiltrates on chest xray)

Constitutional symptoms ☐ YES ☐ NO

Skin ☐ YES ☐ NO

Serositis ☐ YES ☐ NO

Worsening arthritis (give current DAS28) ☐ YES ☐ NO DAS28: _____

Renal involvement ☐ YES ☐ NO

Neurological involvement ☐ YES ☐ NO

Immunological abnormality ☐ YES ☐ NO

Other (specify): _____

Please record result of ANA, ENA, DNA and complement if done, including date/s: _____

Drug Details

Has anti-TNF been stopped due to event? ☐ Yes ☐ No Date stopped (if yes): _____

Has the condition resolved on stopping anti-TNF? ☐ Yes ☐ No

Was the patient taking any other drugs that have been associated with drug induced lupus?

E.g. sulphasalazine, penicillamine ☐ Yes ☐ No (if yes please state below)

Other medication been stopped? ☐ Yes ☐ No (if yes please state below with date stopped)

Did this event require the initiation of or an increased dose of corticosteroid? ☐ Yes ☐ No

**What was the
event outcome?**

☐ Resolved

☐ Resolved with sequelae

☐ Not resolved

☐ Fatal

Has a yellow card been submitted?

YES NO UNKNOWN

(Please circle)

Form completed

By: _____

On: ____/____/____

Please return to: BILAG BR, The University of Manchester, Unit 4 Rutherford House, 40 Pencroft Way, Manchester Science Park, Manchester M15 6SZ.
Or fax to 0161 2751640



BILAG BR Event of Special Interest (ESI) Report HEPATITIS B

Patient Name:

HRN:

PATIENT ID:

Date of Birth:

Biologic at time of event:

Date of Event:

Product Batch Number:

(please tick here if unknown ☐)

Details

Please add any additional information and check the event date and biologic therapy as above.

Peak ALT:

Hepatitis B DNA titre

Please complete the following relating to the current event and prior hepatitis if known:

	Current			Pre registration with BSRBR		
Positive/negative/not tested:	+ve	-ve	Not tested	+ve	-ve	Not tested
HBcAb (core antibody)						
HBsAb (surface antibody)						
HBsAg (surface antigen)						
HBeAg (envelope antigen)						

What was the event outcome?

- ☐ Resolved
☐ Resolved with sequelae
☐ Not resolved
☐ Fatal

Has a yellow card been submitted?

YES NO UNKNOWN

(Please Circle)

Form completed

By: _____
On: ____/____/____

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BILAG BR Event of Special Interest (ESI) Report SERIOUS HAEMORRHAGE

Patient Name:

Date of Birth:

PATIENT ID:

HRN:

Biologic at time of event:

Date of Event:

Product Batch Number: (please tick here if unknown ☐)

Serious Adverse Event when: Death, Hospitalisation, IV Antibiotics, Significant loss of function, Life Threatening or causing congenital malformation.

Event Details: Please provide Diagnosis, Site and any further details available

Medication at time of event:

Was the event pregnancy/ delivery related? YES NO
(If yes please complete pregnancy ESI also)

What was the patient's Lowest Hb recorded:

Does the patient have a known bleeding disorder? YES NO UNKNOWN
If yes please provide details:

Did the event result in?

Hospitalisation YES/ NO **Length of hospitalisation:**

Surgical Procedure YES/ NO **Procedure:**

Transfusion YES/ NO **Details:**

What was the event outcome?

☐ Resolved

☐ Resolved with sequelae

☐ Not resolved

☐ Fatal

Has a yellow card been submitted?

YES NO UNKNOWN

(Please Circle)

Form completed

By: _____

On: ____/____/____

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BILAG BR Event of Special Interest (ESI) Report SERIOUS SKIN REACTION

Patient Name:

Date of Birth:

PATIENT ID:

HRN:

Biologic at time of event:

Date of Event:

Product Batch Number: (please tick here if unknown ☐)

Event Details (please annotate with any additional information)

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 (Circle)
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 state the 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 details

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

Is the patient's biologic 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)

Please attach any skin histology reports.

What was the
event outcome?

- ☐ Resolved
☐ Resolved with sequelae
☐ Not resolved
☐ Fatal

Has a yellow card been submitted?

YES NO UNKNOWN

Form completed

By: _____

On: ____/____/____

Please return to: BILAG BR, The University of Manchester, Unit 4 Rutherford House, 40 Pencroft Way, Manchester Science Park, Manchester M15 6SZ.
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BILAG BR Event of Special Interest (ESI) Report SERIOUS GI ULCER/BLEED/PERFORATION

Patient Name:

Date of Birth:

PATIENT ID:

HRN:

Biologic at time of event:

Date of Event:

Product Batch Number:

(please tick here if unknown ☐)

Event: (Please note any additional information including complications such as peritonitis, ileus, bowel necrosis, fistula, sepsis)

Details:

Haemorrhage ☐ Yes ☐ No

Perforation ☐ Yes ☐ No

Abscess ☐ Yes ☐ No

Site: Small Bowel ☐ Large Bowel ☐ Unknown ☐

Investigations performed:

Please give details/ attach report

CT/ MRI ☐ Yes ☐ No

Other ☐ Yes ☐ No

Endoscopy ☐ Yes ☐ No

On admission did medication include?

NSAID ☐ YES ☐ NO ☐ UNK

Other DMARD ☐ YES ☐ NO ☐ UNK

Oral Corticosteroid ☐ YES ☐ NO ☐ UNK

Antacid/PPI/H2 blocker ☐ YES ☐ NO ☐ UNK

Methotrexate ☐ YES ☐ NO ☐ UNK

Was a surgical procedure required: YES/ NO (PLEASE CIRCLE)

If YES please give details:

Relevant past history

Upper GI ulcer ☐ Yes ☐ No ☐ Unknown Diverticulitis ☐ Yes ☐ No ☐ Unknown

Lower GI ulcer ☐ Yes ☐ No ☐ Unknown Inflammatory Bowel Disease ☐ Yes ☐ No ☐ Unknown

Other GI conditions (please give details):

What was the outcome?

☐ Resolved

☐ Not Resolved

☐ Resolved with sequelae

☐ Fatal

Has a yellow card been submitted? ☐ YES ☐ NO ☐ UNKNOWN

Completed On: ____/____/____
By: _____

Please return to: BILAG BR, University of Manchester, Rutherford House, 40
Pencroft Way, Manchester Science Park, Manchester. M15 6SZ,
or fax to 0161 2751640.



BILAG BR Event of Special Interest (ESI) Report SERIOUS HEPATIC DYSFUNCTION / FAILURE

Patient Name:	Date of Birth:
PATIENT ID:	HRN:
Biologic at time of event: Product Batch Number: _____ (please tick here if unknown <input type="checkbox"/>)	Date of Event:

Event Details (please annotate with any additional information including time course)

What signs and symptoms did the patient have?:

- | | | | |
|-----------------------|------------------------------|-----------------------------|-------------------------------------|
| → Jaundice | <input type="checkbox"/> YES | <input type="checkbox"/> NO | <input type="checkbox"/> DON'T KNOW |
| → Ascites | <input type="checkbox"/> YES | <input type="checkbox"/> NO | <input type="checkbox"/> DON'T KNOW |
| → Coagulopathy | <input type="checkbox"/> YES | <input type="checkbox"/> NO | <input type="checkbox"/> DON'T KNOW |
| → Oesophageal varices | <input type="checkbox"/> YES | <input type="checkbox"/> NO | <input type="checkbox"/> DON'T KNOW |
| → Hypoglycaemia | <input type="checkbox"/> YES | <input type="checkbox"/> NO | <input type="checkbox"/> DON'T KNOW |
| → Encephalopathy | <input type="checkbox"/> YES | <input type="checkbox"/> NO | <input type="checkbox"/> DON'T KNOW |

What investigations were performed?

Did the patient have raised Liver Enzymes? ☐ YES ☐ NO ☐ DON'T KNOW

Please give the highest levels reached:

- | | |
|--------------|--------------------|
| • AST: _____ | • Alk Phos: _____ |
| • ALT: _____ | • Bilirubin: _____ |
| • INR: _____ | |

And the **Lowest** albumin Level: _____

→ Was a liver biopsy performed? ☐ YES ☐ NO

Please give details or attach report

→ Was a CT/MRI/USS of the liver performed? ☐ YES ☐ NO

Please give details or attach report

Medication at time of event:

OTHER (please list):

METHOTREXATE: YES / NO (please circle)

What previous history did the patient have?

●Prior liver disease

Details:

☐ YES ☐ NO ☐ DON'T KNOW

●Excessive alcohol intake

Details:

☐ YES ☐ NO ☐ DON'T KNOW

●Infective hepatitis or other pre-existing infection

Details:

☐ YES ☐ NO ☐ DON'T KNOW

●Drug abuse

Details:

☐ YES ☐ NO ☐ DON'T KNOW**What was the outcome?**☐ Liver transplant☐ Resolved☐ Not Resolved☐ Resolved with sequelae☐ Fatal**Please give details:****Has a yellow card been submitted?**☐ YES ☐ NO ☐ UNKNOWN

Form completed

By: _____

On: ____/____/____

Please return to: BILAG BR, Rutherford House, 40 Pencroft Way,
Manchester Science Park, Manchester. M15 6SZ,
or fax to 0161 2751640.**Thank you for your help!**