MANCHESTER 1824
The University of Manchester

British Society for Rheumatology
Rheumatoid Arthritis Register

BSRBR-RA Event of Special Interest (ESI) Report
SERIOUS HEPATIC DYSFUNCTION / FAILURE

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 including time course)

What signs and symptoms did the patient have?

→ Jaundice	☐ YES	☐ NO	☐ DON'T KNOW
→ Ascites	☐ YES	☐ NO	☐ DON'T KNOW
→ Coagulopathy	☐ YES	☐ NO	☐ DON'T KNOW
→Oesophageal varices	☐ YES	☐ NO	☐ DON'T KNOW
→ Hypoglycaemia	☐ YES	☐ NO	☐ DON'T KNOW
→ Encephalopathy	☐ YES	☐ NO	☐ 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:_____
- ALT:_____
- INR:_____
- Alk Phos:_____
- Bilirubin:_____

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: **METHOTREXATE**: YES / NO (please circle)

OTHER (please list):

What previous history did the patient have?

●Prior liver disease ☐ YES ☐ NO ☐ DON'T KNOW

Details:

●Excessive alcohol intake ☐ YES ☐ NO ☐ DON'T KNOW

Details:

●Infective hepatitis or other pre-existing infection ☐ YES ☐ NO ☐ DON'T KNOW

Details:

●Drug abuse ☐ YES ☐ NO ☐ DON'T KNOW

Details:

Did the patient undergo a liver transplant? (please circle) Yes / No

What was the outcome of the event?

Resolved ☐ Not Resolved ☐ Resolved with sequelae ☐ Fatal ☐

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: _____

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