

**BSRBR-RA Event of Special Interest (ESI) Report
SERIOUS GI ULCER/BLEED/PERFORATION**



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

Event: (Please include any 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):

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

Completed On: ___/___/___ By: _____	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
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