

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

<b>Study ID:</b> <b>HRN:</b> <b>Patient Initials:</b>	<b>Gender:</b> <b>Date of Birth:</b> <b>NHS Number:</b>
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<b>Event Date:</b>	<b>Biologic/biosimilar at time of event:</b> <b>Product Batch Number:</b>
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**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 <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNK	Other DMARD <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNK
Oral Corticosteroid <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNK	Antacid/PPI/H2 blocker <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNK
Methotrexate <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> 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. biologics.register@manchester.ac.uk
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