Tocilizumab Guided Questionnaire
Gastrointestinal Perforation and Related Events

AER:		Local Case ID:	
Site No:		Patient Date of Birth (dd-MMM-yyyy):	
Patient ID/Initials:		Patient Gender:	☐ M ☐ F
Patient Weight	☐ kg ☐ lb	Patient Height	☐ cm ☐ inch

Gastrointestinal perforations and related events have been observed in some patients treated with Tocilizumab.

By filling in this questionnaire, you will help us to understand more fully the risk factors for this condition.

Reporter Information
Name of reporter completing this form: (if other than addressee, provide contact information below)
Health Care Provider? ☐ Yes ☐ No Specify:
Phone Number: Fax Number: Email Address:

Reported Term

Description of the event
Hospital Admission ☐ Yes (Admission Date MM/DD/YYYY): ☐No (Discharge Date MM/DD/YYYY):
Onset Date (MM/DD/YYYY)
Stop Date (MM/DD/YYYY)
Select all that apply: **SERIOUSNESS CRITERIA CLASSIFICATION** ☐**Death** Date of Death (MM/DD/YYYY) ☐**Life-Threatening** (use only if patient was at immediate risk of death due to event) ☐**Initial/Prolonged Hospitalization** ☐**Congenital Anomaly/Birth Defect** ☐**Persistent or Significant Disability** ☐**Medically Significant** (important medical events that may jeopardize the patient and may require

medical/surgical intervention to prevent the other outcomes) ☐ **Non-Serious**	
Related to Tocilizumab?	☐Yes ☐ No
Event led to surgery	☐Yes Please specify: ☐No
Outcome of the event:	☐Persisting ☐ Improved ☐Recovered with sequelae ☐Resolved ☐Unknown ☐Worsened ☐ Death

Drug therapy details – Tocilizumab			
Indication:			
Start Date (MM/DD/YYYY)			
Starting Dose	_____ mg/kg _____ Total monthly dose (mg)		
Route			
Frequency	☐ Monthly ☐Other, please specify:		
History of 4 most recent Infusions prior to Adverse Event (AE)	Date (MM/DD/YYYY)	Dose	Action Taken in response to AE?
			☐Dose maintained ☐Dose decreased ☐Dose interrupted ☐Dose increased ☐Dose discontinued
			☐Dose maintained ☐Dose decreased ☐Dose interrupted ☐Dose increased ☐Dose discontinued
			☐Dose maintained ☐Dose decreased ☐Dose interrupted ☐Dose increased ☐Dose discontinued
			☐Dose maintained ☐Dose decreased ☐Dose interrupted ☐Dose increased ☐Dose discontinued

Treatment for the event		
What treatment was initiated for the event? (including any pre-hospitalization treatment)		
Treatment	Dosing Regimen	Dates of Therapy (MM/DD/YYYY to MM/DD/YYYY)

Risk Factors			
Please indicate if the following conditions are either part of the patient's medical history or are still active conditions.			
Gastric ulcers Specify:	☐History	☐Concurrent	☐Not present
Duodenal ulcers Specify:	☐History	☐Concurrent	☐Not present
Inflammatory bowel disease Specify:	☐History	☐Concurrent	☐Not present
Diverticulosis Specify:	☐History	☐Concurrent	☐Not present
Diverticulitis Specify:	☐History	☐Concurrent	☐Not present
Gastrointestinal obstruction Specify:	☐History	☐Concurrent	☐Not present
Abdominal pain	☐History	☐Concurrent	☐Not present
Abdominal abscess	☐History	☐Concurrent	☐Not present
Fistula	☐History	☐Concurrent	☐Not present
Gastrointestinal bleeding Specify:	☐History	☐Concurrent	☐Not present
Cancer Specify:	☐History	☐Concurrent	☐Not present
Smoking	☐History	☐Concurrent	☐Not present
Alcohol abuse	☐History	☐Concurrent	☐Not present
Abdominal Surgery Specify:	☐History	☐Concurrent	☐Not present
Colonoscopy	☐History	☐Concurrent	☐Not present
Endoscopy	☐History	☐Concurrent	☐Not present
Other Please Specify:	☐History	☐Concurrent	☐Not present

Laboratory tests/ Imaging

Please provide SI (International System of Units) if available. Otherwise, as reported.

Please attach all laboratory results and imaging tests. ☐Labs Attached

Please indicate if any of the following tests have been performed, and the result:

	Baseline Value (Prior to TCZ Use)	Date of Baseline Test (MM/DD/YYYY)	Date of Test (MM/DD/YYYY)	Test Results (include units)	Reference Range (If Applicable)	Pending?
CBC						☐Yes
Laparoscopy						☐Yes
Colonoscopy						☐Yes
Sigmoidoscopy						☐Yes
EGD (Esophagogastro-duodenoscopy)						☐Yes
CT Scan						☐Yes
MRI						☐Yes
Other						☐Yes

Past/Concomitant Medications
☐Medication List Attached

		Dose	Route	Frequency	Past, Concomitant, or N/A
Methotrexate	☐Yes ☐ No				☐Past ☐Concomitant ☐N/A
Other DMARDs Specify:	☐Yes ☐ No				☐Past ☐Concomitant ☐N/A
Biologic DMARDs Specify:	☐Yes ☐ No				☐Past ☐Concomitant ☐N/A
NSAIDs Specify:	☐Yes ☐ No				☐Past ☐Concomitant ☐N/A
Corticosteroids Specify:	☐Yes ☐ No				☐Past ☐Concomitant ☐N/A
PPIs Specify:	☐Yes ☐ No				☐Past ☐Concomitant ☐N/A
H2 blockers Specify:	☐Yes ☐ No				☐Past ☐Concomitant ☐N/A
Stool softeners Specify:	☐Yes ☐ No				☐Past ☐Concomitant ☐N/A
Antibiotics	☐Yes ☐ No				☐Past ☐Concomitant ☐N/A
Surgery	☐Yes ☐ No				☐Past ☐Concomitant ☐N/A
Other Please specify:	☐Yes ☐ No				☐Past ☐Concomitant ☐N/A

Please provide any further relevant information about the Adverse Event. Please indicate if there have been any significant changes from the initial report.

Thank you for completing this form.

Completed by:

Name: ..... Position: .....

Signature: ..... Date: .....

E-mail: .....