Tocilizumab Guided Questionnaire
Spontaneous or Serious/Non Serious Bleeding Event

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

Bleeding events have been observed in some patients treated with Tocilizumab. This guided questionnaire is intended to be used with both internal and external haemorrhagic events including haemorrhagic strokes. By filling in this questionnaire, you will help us to understand more fully the risk factors for this condition.

Thank you for your assistance. We look forward to your reply.

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): (Discharge Date MM/DD/YYYY):	☐No
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
Outcome of the event:	☐Persisting ☐ Improved ☐Recovered with sequelae ☐Resolved ☐Unknown ☐Worsened ☐Death
Was the bleeding event associated with a platelet count of <100,000/mm^3?	☐No ☐Yes: Provide Date of abnormal labs (MM/DD/YYYY): ☐Unknown
Did dose modification occur in association with lab abnormality?	☐No ☐Yes: Provide Date of dose modification (MM/DD/YYYY): ☐Unknown

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)		
Endoscopic Treatment		
Surgery		
Treatment	**Dosing Regimen**	**Dates of Therapy (MM/DD/YYYY to MM/DD/YYYY)**

Please attach all laboratory results (haemoglobin, hematocrit, platelet count, etc) and imaging tests. Please provide SI (International System of Units) if available. Otherwise, as reported.

☐ **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?**
Fecal Occult Blood Test						☐Yes
Urinalysis						☐Yes
INR						☐Yes
CT Scan						☐Yes
MRI						☐Yes
Colonoscopy						☐Yes
Endoscopy						☐Yes
Other Please specify:						☐Yes

Risk Factors			
Please indicate if the following conditions are either part of the patient's medical history or are still active conditions.			
Haemophilia	☐History	☐Concurrent	☐Not present
Von Willebrand's disease	☐History	☐Concurrent	☐Not present
Previous Event of Haemorrhage Specify:	☐History	☐Concurrent	☐Not present
Other, please specify:	☐History	☐Concurrent	☐Not present

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
Corticosteroids Specify:	☐Yes ☐ No				☐Past ☐Concomitant ☐N/A
Aspirin/ anti-platelet Specify:	☐Yes ☐ No				☐Past ☐Concomitant ☐N/A
NSAIDs Specify:	☐Yes ☐ No				☐Past ☐Concomitant ☐N/A
Coumarin/Coumadin	☐Yes ☐ No				☐Past ☐Concomitant ☐N/A
Heparin	☐Yes ☐ No				☐Past ☐Concomitant ☐N/A
SSRIs Specify:	☐Yes ☐ No				☐Past ☐Concomitant ☐N/A
Ginkgo Biloba	☐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: .....