Tocilizumab Guided Questionnaire
Infections (Including Opportunistic Infections)

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

Infections 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	
Outcome of the event:	☐Persisting ☐ Improved ☐Recovered with sequelae ☐Resolved ☐Unknown ☐Worsened ☐Death
Was the patient neutropenic at the current time of the serious or opportunistic infectious event ?	☐No ☐Yes: Provide lab results including Date of abnormal labs if available(MM/DD/YYYY): ☐Unknown
Was the infection associated with an ANC of <1000?	☐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)		
Treatment	Dosing Regimen	Dates of Therapy (MM/DD/YYYY to MM/DD/YYYY)

Please attach all laboratory results [blood, sputum, all available cultures, gram stain, Complete Blood Count with Differential, CRP, ESR] 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 below:

	Baseline Value (Prior to TCZ Use)	Date of Baseline Test (MM/DD/YYYY)	Lab results at time of event including Date of Test (MM/DD/YYYY)	Test Results (include units)	Reference Range (If Applicable)	Pending?
Blood Culture/Stool/Urine/ Cerebrospinal fluid						☐Yes
Complete Blood Count with Differential						☐Yes
Chest X-Ray						☐Yes
CT Scan						☐Yes
CRP (C-reactive protein)						☐Yes
ESR (erythrocyte sedimentation rate)						☐Yes
PPD Results						☐Yes
PCR						☐Yes
Acid Fast Bacilli						☐Yes
Histology						☐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.			
Diabetes Mellitus	☐History	☐Concurrent	☐Not present
HIV Infection	☐History	☐Concurrent	☐Not present
Felty's syndrome: long standing RA, splenomegaly, and low WBC Specify:	☐History	☐Concurrent	☐Not present
Splenectomy	☐History	☐Concurrent	☐Not present
Indwelling catheter	☐History	☐Concurrent	☐Not present
Previous Infection? Specify:	☐History	☐Concurrent	☐Not present
Recent Travel? Specify:	☐History	☐Concurrent	☐Not present
Other Please specify:	☐History	☐Concurrent	☐Not present

Has the patient ever received TB prophylaxis or active treatment? If yes, provide details below.				
Product Name	**Prophylactic or Active**	**Dose**	**Date started**	**Date stopped**

	Treatment?			

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
Other Please specify:	☐Yes ☐ No				☐Past ☐Concomitant ☐N/A

In the few weeks following the infection, what was the specific Immunoglobulin titer to the infectious agent (if available):		
IgG	Date (MM/DD/YYYY)	Result:
IgM	Date (MM/DD/YYYY)	Result:
IgA	Date (MM/DD/YYYY)	Result:
Other tests: Please specify:	Date (MM/DD/YYYY)	Result:

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: .....