Tocilizumab Guided Questionnaire
Malignancy

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

Malignancy has 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

Provide anatomical site **(Please provide biopsy, pathology, and biomarker results if available)**	

Description of the event		
Event led to	1. surgery	☐Yes ☐ No
	2. radiotherapy	☐Yes ☐ No
	3. chemotherapy	☐Yes ☐ No
Hospital Admission ☐ Yes (Admission Date MM/DD/YYYY): (Discharge Date MM/DD/YYYY):		☐No
Onset Date (MM/DD/YYYY)		
Stop Date (MM/DD/YYYY)		

Posit

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

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.			
Smoking	☐History	☐Concurrent	☐Not present
Alcohol use	☐History	☐Concurrent	☐Not present
Family history of cancer Specify:	☐History	☐Concurrent	☐Not present
Chemical exposure	☐History	☐Concurrent	☐Not present
Sunlight exposure (UV) Specify:	☐History	☐Concurrent	☐Not present
Ionizing radiation exposure Specify:	☐History	☐Concurrent	☐Not present
HIV infection	☐History	☐Concurrent	☐Not present
EBV infection	☐History	☐Concurrent	☐Not present
HTLV infection	☐History	☐Concurrent	☐Not present
Other infections 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

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

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

☐**Labs Attached**

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: .....