Tocilizumab Guided Questionnaire
Medically Significant Hepatic 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

Hepatic 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

Outcome of the event:	☐Persisting ☐ Improved ☐Recovered with sequelae ☐Resolved ☐Unknown ☐Worsened ☐Death
Was the hepatic event associated with ALT/AST >3xULN?	☐No ☐Yes: Provide Date of abnormal labs (MM/DD/YYYY): ☐Unknown
Was the hepatic event associated with total bilirubin of >2xULN?	☐No ☐Yes: Provide Date of abnormal labs (MM/DD/YYYY): ☐Unknown
Did TCZ dose modification occur in association with lab abnormality?	☐No ☐Yes: Provide Date of dose modification (MM/DD/YYYY): ☐Unknown
Did DMARD 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)**

Risk Factors			
Please indicate if the following conditions are either part of the patient's medical history or are still active conditions.			
Pre-existing hepatobiliary Disorder Specify:	☐History	☐Concurrent	☐Not present
Pancreatic Disorder Specify:	☐History	☐Concurrent	☐Not present
Drug Allergy Specify:	☐History	☐Concurrent	☐Not present
Previous Drug Reactions Specify:	☐History	☐Concurrent	☐Not present
Auto-Immune Disease Specify:	☐History	☐Concurrent	☐Not present
Surgical Procedures Specify:	☐History	☐Concurrent	☐Not present
Blood Transfusion Specify:	☐History	☐Concurrent	☐Not present
Alcohol use Specify:	☐History	☐Concurrent	☐Not present
Tattoo Specify:	☐History	☐Concurrent	☐Not present
Acupuncture Specify:	☐History	☐Concurrent	☐Not present
IV Drug Abuse Specify:	☐History	☐Concurrent	☐Not present
Sexually Transmitted Diseases Specify:	☐History	☐Concurrent	☐Not present
Diabetes Mellitus Specify:	☐History	☐Concurrent	☐Not present

Obesity Specify:	☐History	☐Concurrent	☐Not present
Non-alcoholic steatohepatitis Specify:	☐History	☐Concurrent	☐Not present
Viral hepatitis Specify:	☐History	☐Concurrent	☐Not present
Family History of Liver Disease Specify:	☐History	☐Concurrent	☐Not present
Recent Travel to Endemic areas for viral hepatitis Specify:	☐History	☐Concurrent	☐Not present
CHF	☐History	☐Concurrent	☐Not present
Other: Please specify:	☐History	☐Concurrent	☐Not present

Please attach all laboratory results (ALT, ALT, Indirect bilirubin, INR, Alkaline phosphatise, albumin, CBC, CRP, eosinophils 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?**
ANA						☐ Yes
Liver biopsy* Please obtain biopsy report if available						☐ Yes
CT Scan						☐ Yes
MRI						☐ Yes
Ultrasound						☐ Yes
Other: Please specify:						☐ Yes

Serology Results

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

Test	**Conducted?**	**Results**	**Date (MM/DD/YYYY)**
Hepatitis A	☐ Yes☐ No		
Hepatitis B	☐ Yes☐ No		
Hepatitis C	☐ Yes☐ No		

Hepatitis D	☐ Yes☐ No		
Anti-CMV	☐ Yes☐ No		
Anti-EBV	☐ Yes☐ No		
Anti-Nuclear Ab	☐ Yes☐ No		
Anti-mitochondrial Ab	☐ Yes☐ No		
Other: Please specify:	☐ Yes☐ No		

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
Statins Specify:	☐ Yes ☐ No				☐Past ☐Concomitant ☐N/A
Acetaminophen	☐ Yes ☐ No				☐Past ☐Concomitant ☐N/A
Antibiotic Specify:	☐ Yes ☐ No				☐Past ☐Concomitant ☐N/A
Other: Please specify:	☐ Yes ☐ No				☐Past ☐Concomitant ☐N/A

Thank you for completing this form.

Completed by:

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

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

E-mail: .....