Tocilizumab Guided Questionnaire
Stroke

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

Stroke 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

Description of the event
Type of Stroke: ☐ Ischemic: ☐ Hemorrhagic ☐ Other/unknown—please specify
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

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 (fasting cholesterol panel, cardiac enzymes, platelets) 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?**
CT Scan						☐ Yes
MRI						☐ Yes
Carotid Doppler						☐ Yes
MRA (Magnetic Resonance Angiogram)						☐ Yes
Cerebral Arteriogram						☐ 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.			
Prior Stroke Specify:	☐History	☐Concurrent	☐Not present
Prior TIA Specify:	☐History	☐Concurrent	☐Not present
Prior Heart Attack Specify:	☐History	☐Concurrent	☐Not present
Hypertension	☐History	☐Concurrent	☐Not present

Smoking Specify:	☐History	☐Concurrent	☐Not present
Diabetes Mellitus	☐History	☐Concurrent	☐Not present
Coronary artery Disease Specify:	☐History	☐Concurrent	☐Not present
Atrial Fibrillation	☐History	☐Concurrent	☐Not present
Sickle Cell Anemia	☐History	☐Concurrent	☐Not present
Hypercholesterolemia	☐History	☐Concurrent	☐Not present
Physical Inactivity	☐History	☐Concurrent	☐Not present
Obesity	☐History	☐Concurrent	☐Not present
Low platelet count	☐History	☐Concurrent	☐Not present
Cardiac valvular disease	☐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
Lipid lowering Medications Specify:	☐ Yes ☐ No				☐Past ☐Concomitant ☐N/A
Antihypertensive medications Specify:	☐ Yes ☐ No				☐Past ☐Concomitant ☐N/A
Aspirin/ anti-platelet Specify:	☐ 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: .....