Tocilizumab Guided Questionnaire
Demyelination Events

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

Demyelination 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): (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

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

Laboratory tests/ Imaging

Please provide SI (International System of Units) if available. Otherwise, as reported.

Please attach all laboratory results and imaging tests. ☐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?**
CBC/ Differential WBC Count						☐ Yes
CRP						☐ Yes
CSF analysis (Please include protein, glucose, cell count, IgG, virus results)						☐ Yes
Brain and Spine CT Scan Number of lesions in white matter: Location of the lesions: Size of the lesions:						☐ Yes
MRI						☐Yes
Evoked potentials/ Electro-diagnostic studies Please specify if auditory, visual, or somatosensory						☐ 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.

Immunodeficiency Specify:	☐History	☐Concurrent	☐Not present

Viral infection Specify:	☐History	☐Concurrent	☐Not present
JC Virus	☐History	☐Concurrent	☐Not present
Lyme Disease	☐History	☐Concurrent	☐Not present
Other opportunistic infections Specify:	☐History	☐Concurrent	☐Not present
Other infections Specify:	☐History	☐Concurrent	☐Not present
SLE	☐History	☐Concurrent	☐Not present
Collagen vascular disease	☐History	☐Concurrent	☐Not present
Complications from previous immunosuppressive medication/conditions Specify:	☐History	☐Concurrent	☐Not present
Diabetes mellitus	☐History	☐Concurrent	☐Not present
Arteriosclerosis Specify:	☐History	☐Concurrent	☐Not present
Multiple Sclerosis	☐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 Specify:	☐ Yes ☐ No				☐Past ☐Concomitant ☐N/A
NSAIDs 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: .....