Tocilizumab/Roactemra Guided Questionnaire
Anaphylaxis/Serious hypersensitivity reaction

AER:		Local Case ID:	
Site No:		Patient Date of Birth (MM/DD/YYYY)	
Patient ID/Initials:		Patient Gender:	☐ M ☐ F
Tocilizumab (Actemra®) use	☐IV ☐SC	Patient Height	☐ cm ☐ inch
If tocilizumab was received as SC	☐Home use ☐Health care setting use	Patient Weight	☐ kg ☐ lb

Anaphylaxis/Serious hypersensitivity reaction has been observed in some patients treated with tocilizumab. By filling in this questionnaire, you will help us to better characterize it.

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(s): please provide all the symptoms experienced at the time of event/reaction

Description of the event	
Date of the reported event (MM/DD/YYYY):	
Date of most recent tocilizumab dose (MM/DD/YYYY):	
Related to tocilizumab? ☐ Yes ☐ No	
Related to other allergens (drugs, food, insect, etc….): ☐ Yes ☐ No If yes, please specify:----------	
Time to onset of reaction from the initiation of the most recent dose of tocilizumab (minutes/hours):	
Vital signs (HR, BP): Before infusion/injection	Vital Signs (HR, BP): At the time of anaphylaxis/serious hypersensitivity
Treatment given for the event	☐ Yes ☐ No
If Yes, please complete the "**Treatment for the event"** section	

Hospital Admission ☐ Yes (Admission Date MM/DD/YYYY): (Discharge Date MM/DD/YYYY): ☐ No	
Outcome of the event:	☐Persisting ☐ Improved ☐Recovered with sequelae ☐Resolved ☐Unknown ☐Worsened ☐Death
Resolution date of the reported event (MM/DD/YYYY)	
Is the reported event : ☐ Serious ☐ Non-Serious	
If serious, please select the criteria as below:	
Select all that apply: **Seriousness criteria:** ☐ **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)	

Pre-Medications ☐**Medication List Attached**				
Medication given prior to infusion/injection only			Dose	Route
Corticosteroids Specify:	☐Yes	☐No		
Antihistamines Specify:	☐Yes	☐ No		
Antipyretics Specify:	☐Yes	☐ No		
Other Please specify:	☐ Yes	☐ No		

Drug therapy details – Tocilizumab	
Indication:	
Start Date (MM/DD/YYYY)	
Dose for IV (mg/kg)	☐ 4 ☐ 8 ☐ 10 ☐ 12 ☐ Other (specify)…….
Frequency for IV	☐Once every two weeks ☐Once every four weeks ☐ Other
Frequency for SC (162mg)	☐ Q1W (once a week) ☐ Q2W(once every two weeks)

History of 4 most recent Infusions/injections prior to Adverse Event (AE)		Tocilizumab administration			
	Date (MM/DD/YYYY)	Dose (mg/kg or mg)	Route (IV or SC)	Frequency	Did the patient experience any reaction with this dose
					☐Yes, ☐No Specify:
					☐Yes ☐No Specify:
					☐Yes ☐No Specify:
					☐Yes ☐No Specify:
					☐Yes ☐No Specify:
					☐Yes ☐No Specify:

Has the treatment been missed or interrupted for any reason: ☐Yes ☐No	Reason for missed or interrupted dose	Dates (MM/DD/YYYY)	
		From:	To

Treatment for the event				
What treatment was initiated for the event? (including any pre-hospitalization treatment)				
Treatment	Dose	Route of administration	Dates of Therapy (MM/DD/YYYY	
			From	To
Epinephrine ☐Yes ☐No				
Corticosteroids ☐Yes ☐No Specify:				
Antihistamines ☐Yes ☐No Specify:				
Fluid resuscitation ☐Yes ☐No				
Oxygen ☐Yes ☐No				
Other ☐Yes ☐No Specify:				

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:

	Date of Baseline Test (MM/DD/YYYY)	Baseline Value (Prior to TCZ Use)	Date of Test (MM/DD/YYYY)	Test Results (include units)	Reference Range (If applicable)	Test Results Pending
Serum tryptase	NA	NA				☐Yes
Anti-tocilizumab antibody test						☐Yes
Serum histamine	NA	NA				☐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.

Any previous hypersensitivity reaction to other drugs: ☐ Yes ☐ No
Please describe the detail of the event(s) including symptoms and drug(s) involved:

Any previous hypersensitivity reaction to tocilizumab: ☐ Yes ☐ No
Please describe the detail of the event(s) including symptoms:

☐Other Allergies: ☐Food, ☐Insect bite ☐Latex ☐Intravenous radiocontrast media ☐Others (specify):	☐History	☐Concurrent	☐Not present
Asthma	☐History	☐Concurrent	☐Not present
Hypertension	☐History	☐Concurrent	☐Not present
Any cardiac condition Please specify:	☐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
Ace Inhibitors Specify:	☐ Yes ☐ No				☐Past ☐Concomitant ☐N/A
Antihistamines Specify:	☐Yes ☐ No				☐Past ☐Concomitant ☐N/A
Beta- blockers 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: .....