Global: Tocilizumab in COVID-19 Reporting Form

Please email to: south_africa.drugsafety@roche.com

Instructions:
This form is specifically and only to capture data and adverse events related to Tocilizumab treatment in COVID-19. At present, there is no robust published clinical trial evidence regarding the safety or efficacy of Tocilizumab in treatment of COVID-19 and no health authority has approved Tocilizumab for this use. Healthcare professionals should make their own medical judgement in defining benefit:risk for each individual patients under their care.

Once completed, forward the form to your Roche Local Safety Unit (LSU) or to Roche Safety Operations as applicable.

1 REPORTER DETAILS

Note: If available, please provide reporter's occupation. If data privacy allows please provide name, address and/or phone number.

Reporter First Name:		**Occupation:**	
Complete Address including ZIP code:		☐ Physician (specify specialty): ☐ Pharmacist ☐ Nurse ☐ Consumer/Patient	☐ Legal ☐ Company Representative ☐ Other (specify):
Contact detail (e.g. email, telephone)			

2 PATIENT DETAILS

Note: If data privacy allows please provide at least one descriptor. Please ensure the patient's age or age group is captured wherever possible.

Initials:		**Sex**	☐ ☐ Male ☐ Female Unknown		
Weight:	☐ kg ☐ lb	**Date of Birth:**	dd/MMM/yyyy	**or age at time of event:**	
Ethnic Origin:	☐ Asian ☐ Black ☐ Caucasian ☐ Hispanic ☐ Other (specify):				
Any important medical conditions?	☐ Yes ☐ No	**If yes, please specify which:**			

3 COVID-19: CLINICAL COURSE PRIOR TO TOCILIZUMAB ADMINISTRATION

Infection Onset date or duration	Chest CT or Chest X-ray changes?	Covid-19 test positive?	IL-6 tests performed?	**Intensity of care prior to treatment with Tocilizumab**			
				Supplemental Oxygen Therapy	Treated in an ICU?	Ventilator support?	Need for vasopressors or dialysis or other?
dd/MMM/yyyy Days	☐ Yes ☐ No Details:	☐ Yes ☐ No Results:	☐ Yes ☐ No Results:	☐ Yes ☐ No	☐ Yes ☐ No Details:	☐ Yes ☐ No Details:	☐ Yes ☐ No Specify:

4 TOCILIZUMAB ADMINISTRATION DETAILS

Indication / Condition (for which the product has been prescribed e.g. COVID-19 pneumonia)

Dose and Unit	**Route**	**Frequency**	**Start Date** dd/MMM/yyyy	**Stop Date** dd/MMM/yyyy (or ongoing)	**Batch / Lot Number**

5 COVID-19: DESCRIBE BELOW IN DETAIL THE CLINICAL COURSE AFTER TOCILIZUMAB ADMINISTRATION INCLUDING PATIENT RECOVERY STATUS:

Global: Tocilizumab in COVID-19 Reporting Form

Please email to: south_africa.drugsafety@roche.com

6 SUSPECTED ADVERSE DRUG EVENT (S) AFTER TOCILIZUMAB ADMINISTRATION

Note: if in your opinion, patient experienced adverse events due to other concomitant drugs other than Tocilizumab, please describe in Additional Information section 8

Adverse Event (AE) (write NA below if no adverse event reported)	**Onset Date dd/MMM/yyyy**	**Outcome** (enter number as per the key below)	**Resolved / Improved Date dd/MMM/yyyy**	**Seriousness** (enter number as per the key below)	**Causality for Tocilizumab Y=Yes, N=No, U=Unknown, NP=Not Provided** If causality is unknown, specify "unknown" and add further details in Section 8

Key for outcomes:	**1. Fatal**	**4. Recovered/Resolved with sequelae**
	2. Not Recovered/Not Resolved	**5. Recovering/Resolving**
	3. Recovered/Resolved	**6. Unknown**
Key for seriousness:	**1. Death** (if yes, provide date): dd/MMM/yyyy **2. Life-Threatening** (use only if patient was at immediate risk of death due to adverse event) **3. Congenital Anomaly/Birth Defect** **4. Persistent or Significant Disability**	**6. Initial/Prolonged Hospital Admission** **7. Medically Significant** (important medical event that may jeopardize the patient and may require medical/surgical intervention to prevent the other outcomes) **8. Non-serious**

7 TEST(S) PERFORMED TO EVALUATE ADVERSE EVENT (S) OR CLINICAL OUTCOME OF COVID-19

If possible, include baseline results prior to product administration. If required, continue in Additional Relevant Information, Section 8.

Test	**Date of Test dd/MMM/yyyy**	**Test Result** (include units if applicable)	**Reference Range**	**Result Pending?**
				☐
				☐

8 ADDITIONAL RELEVANT INFORMATION INCLUDING ADVERSE EVENTS DUE TO OTHER CONCOMITANT DRUGS, IF KNOWN

Note: Clearly indicate the suspect drug, if other than Tocilizumab and provide a description of the adverse event(s), severity, causality, treatment for adverse event(s) and outcome.

ROCHE USE ONLY OR VENDORS ACTING ON BEHALF OF ROCHE

LRN:		**AER:**	
Local Received Date:	dd/MMM/yyyy	**Company Received Date:**	dd/MMM/yyyy
Report Type:	☐ Initial ☐ Follow-Up ☐ Spontaneous ☐ Literature ☐ Other (specify):	**Ancillary Documentation?**	☐ Yes ☐ No
		Supplementary Form attached?	☐ Yes ☐ No