NSW TAG
NSW Therapeutic Advisory Group Inc.
Advancing quality use of medicines in NSW

This form has been extracted from an online form developed by NSW TAG. The information on the first and last page of this form do not apply to the PDF format completion of this form.

Tocilizumab IPU Adverse Events and Clinical Outcomes Report for original IPU applicant (or delegate) completion

Please read before you begin:

- It is recommended that the respondent familiarises themselves with the questions and the information required in this online form BEFORE proceeding (scroll down to view all questions).
- The form can only be completed in one session.
    - You cannot save, close and come back to the report at a later time (if you are called away, the form will remain open unless your browser is closed).
- **Provide a response to each applicable question.**
- Completion of this report may take approximately 5-15 minutes.

It is recommended that this report form is completed within 2 weeks of tocilizumab cessation, discharge or death.

1. *Enter the 'IPU application code' unique to this patient
(use the same code that was selected in the IPU application submission with suggested template Toci_LHD_MRN_DATEofADMISSION) [Question ID: 43753]

2. *What is today's date? (date format: dd/mm/yyyy) [Question ID: 25413]

Section A. Clinician's details

3. *Full name of clinician providing report [Question ID: 25152]

4. *Are you the same clinician who made the original IPU application? [Question ID: 25151]

- O Yes *(jump to question **9**)*
- O No *(jump to question **5**)*

5. Clinician's email address [Question ID: 25153]

6. Clinician's contact phone number (extension and/or mobile number) [Question ID: 25154]

7. Clinician's specialty [Question ID: 43754]

- O Haematologist *(jump to question **9**)*
- O Immunologist *(jump to question **9**)*
- O Infectious Disease Physician *(jump to question **9**)*
- O Intensivist *(jump to question **9**)*
- O Respiratory Physician *(jump to question **9**)*
- O Other, please specify *(jump to question **8**)*

8. If other specialty, please specify [Question ID: 25156]

Section B. Patient Demographics

9. *Patient's initials [Question ID: 43755]

10. *Patient's MRN [Question ID: 25158]

11. *What date was the patient admitted to hospital? [Question ID: 43756]

Section C. Tocilizumab Details

12. *What date was tocilizumab commenced? [Question ID: 43758]

13. *Actual dosing of tocilizumab treatment (i.e. dose and number of doses administered) [Question ID: 43759]

- O 800 mg tocilizumab x 1 dose *(jump to question **15**)*
- O 800 mg tocilizumab x 2 doses *(jump to question **15**)*
- O 600 mg tocilizumab x 1 dose *(jump to question **15**)*
- O 600 mg tocilizumab x 2 doses *(jump to question **15**)*
- O 400 mg tocilizumab x 1 dose *(jump to question **15**)*
- O 400 mg tocilizumab x 2 doses *(jump to question **15**)*
- O Other (please provide details in next question) *(jump to question **14**)*

14. If other, please specify dosing (i.e. dose, number of dose(s) and reason) [Question ID: 43760]

15. *If the actual dosing was different to that proposed in the approved IPU application, provide details (use N/A if dosing not different)

Also include information if:

- infusion incomplete/ceased early
- still ongoing/additional doses planned
- dose was adjusted and why
- consent to treatment withdrawn
- still ongoing/additional doses planned
- contraindication identified
- adverse drug effect experienced (identify here and provide details in section E)
- death occurred

[Question ID: 43761]

Section D. Concomitant Therapy

16. *Was the patient acutely commenced on any of the listed therapies during hospitalisation with COVID-19? [Question ID: 43764]

- ☐ Antiviral therapy
- ☐ Corticosteroid (not topical)
- ☐ Immunomodulator other than tocilizumab
- ☐ Antibacterial therapy
- ☐ Antithrombotic therapy
- ☐ Antifungal therapy
- ☐ Convalescent plasma
- ☐ Hyperimmune immunoglobulin
- ☐ ACE inhibitor
- ☐ Sartan
- ☐ Statin
- ☐ Other therapy (specify in next question)
- ☐ The patient was not commenced on any of the listed medicines above

17. Provide details of relevant therapies selected in the previous question, including if it was part of a clinical trial [Question ID: 43765]

18. *Did any potential or actual drug interactions impact the management of COVID-19 in this patient? [Question ID: 43767]

- ○ No relevant drug interactions *(jump to question **20**)*
- ○ Yes, interaction(s) involving tocilizumab *(jump to question **19**)*
- ○ Yes, interaction(s) involving other COVID-19 therapies *(jump to question **19**)*
- ○ Yes, interaction(s) involving tocilizumab AND other COVID-19 therapies *(jump to question **19**)*

19. Provide details of drug interaction(s) [Question ID: 25169]

Section E. Possible or Likely Adverse Effects Due to Tocilizumab

20. *Did the patient experience any adverse effects (possible or likely) due to tocilizumab use? [Question ID: 43779]

◯ Yes *(jump to question **21**)*

◯ No *(jump to question **44**)*

21. Select the adverse effects, which were possible or likely due to tocilizumab use (more than one answer may be selected) [Question ID: 43768]

☐ Infusion-related reactions (within 24 hours of IV infusion; including but not limited to hypertension, headache, rash)

☐ Headache

☐ Possible allergic reaction, including anaphylactic reactions and angioedema

☐ Mouth ulcers

☐ Gastritis

☐ Gastrointestinal perforation

☐ Dyspnoea

☐ Cough

☐ Pulmonary fibrosis

☐ Secondary opportunistic infection, out of keeping with clinical disease

☐ Hepatotoxicity - increase in LFTs greater than or equal to 5 times upper limit of normal

☐ Serious hepatotoxicity (including acute liver failure, hepatitis and jaundice or requiring liver transplant)

☐ Pancreatitis

☐ Hypofibrinogenaemia

☐ Severe thrombocytopenia, out of keeping with clinical disease

☐ Severe neutropenia, out of keeping with clinical disease

☐ Antibodies to tocilizumab

☐ Death

☐ Other (please provide details in next section)

You are required to provide details for each adverse effect identified. If there are more than TWO adverse effects, a free text field to provide details of these additional adverse effects follows.

Section E continued.
Details of Possible/Likely Adverse Effects Due to Tocilizumab

First adverse effect

22. What was the adverse effect?
(Name the adverse effect only, further details to be provided below) [Question ID: 27432]

23. What was the likelihood that this adverse effect was due to tocilizumab use? [Question ID: 25182]

- O Possibly
- O Likely
- O Don't know

24. What was the timing of onset of the adverse effect after the initial tocilizumab dose was administered (in hours/minutes as applicable)? [Question ID: 25177]

25. What was the severity of the adverse effect? [Question ID: 43780]

- O Mild, no treatment required *(jump to question **27**)*
- O Moderate to Severe, treatment required *(jump to question **26**)*
- O Life-threatening *(jump to question **26**)*
- O Don’t know, no treatment required *(jump to question **27**)*

26. Provide details of treatment given for the adverse effect including relevant laboratory results and/or diagnostic procedures [Question ID: 25415]

27. Has the patient recovered from the adverse effect? [Question ID: 43781]

- O Yes *(jump to question **28**)*
- O No *(jump to question **29**)*
- O Don't know *(jump to question **29**)*

28. How long did it take before the patient recovered from the adverse effect (minutes/hours/days)? [Question ID: 25180]

29. Did the adverse effect prolong the hospitalisation or cause death? [Question ID: 43769]

- O Yes
- O No
- O Don't know

30. Provide further details of the adverse effect
(Please provide as much detail as possible and include any results of relevant laboratory data and other investigations, monitoring required etc.) [Question ID: 25176]

31. Was a possible or likely second adverse effect experienced by the patient? [Question ID: 43782]

- O Yes *(jump to question **32**)*
- O No *(jump to question **43**)*

Section E continued.
Details of Possible/Likely Adverse Effects Due to Tocilizumab

Second adverse effect

32. What was the adverse effect?
(Name the adverse effect only, further details to be provided below) [Question ID: 27433]

33. What was the likelihood that this adverse effect was due to tocilizumab use? [Question ID: 25190]

- O Possibly
- O Likely
- O Don't know

34. What was the timing of onset of the adverse effect after the initial tocilizumab dose was administered (in hours/minutes as applicable)? [Question ID: 25185]

35. What was the severity of the adverse effect? [Question ID: 43783]

- O Mild, no treatment required *(jump to question **37**)*
- O Moderate to Severe, treatment required *(jump to question **36**)*
- O Life-threatening *(jump to question **36**)*
- O Don't know, no treatment required *(jump to question **37**)*

36. Provide details of treatment given for the adverse effect including relevant laboratory results and/or diagnostic procedures [Question ID: 25416]

37. Has the patient recovered from the adverse effect? [Question ID: 43784]

- O Yes *(jump to question **38**)*
- O No *(jump to question **39**)*
- O Don't know *(jump to question **39**)*

38. How long did it take before the patient recovered from the adverse effect (minutes/hours/days)? [Question ID: 25188]

39. Did the adverse effect prolong the hospitalisation or cause death? [Question ID: 43770]

- O Yes
- O No
- O Don't know

40. Provide further details of the adverse effect
(Please provide as much detail as possible and include any results of relevant laboratory data and other investigations, monitoring required etc.) [Question ID: 25184]

41. Were any other adverse effects due to tocilizumab (possible or likely) experienced by the patient? (if **Yes**, jump to question **42** ; if **No**, jump to question **43**) [Question ID: 43785]

- O Yes
- O No

Section E continued.
Details of Possible/Likely Adverse Effects Due to Tocilizumab

Additional adverse drug effects (three or more)

42. Please provide a free text description of all additional adverse effects identified. Include the following information:
(If helpful, copy and paste the dot points below in your response)

- Name the adverse effect
- Likelihood that this adverse was due to tocilizumab: [possibly/ likely/ don't know]
- Timing of onset of the adverse effect after initial tocilizumab administration: [hours/minutes, as applicable]
- Severity of the adverse effect: [mild, no treatment required; moderate to severe, treatment required; life-threatening; don't know, no treatment required]
- Provide details of administered treatment for the adverse effect including relevant laboratory results and/or diagnostic procedures: [provide details or N/A]
- Recovery from the adverse effect? [yes/ no/ don't know]
- Time to recovery from the adverse effect: [minutes/hours/days]
- Prolongation of hospitalisation or caused death by adverse effect: [yes/ no/ don't know]
- Any other relevant details of the adverse effect (include results of relevant laboratory data and other investigations, monitoring required etc.)

[Question ID: 43771]

Section E continued. Possible/Likely Adverse Effects Due to Tocilizumab

43. Were adverse effect(s) reported? [Question ID: 25194]

- O No
- O Yes, reported to both the TGA and the hospital's adverse events reporting system
- O Yes, reported within the hospital's adverse events reporting system
- O Yes, reported to the TGA
- O Not sure

Section F. Clinical Outcomes

44. *Select the current clinical status of the patient

Refer to National COVID-19 Clinical Evidence Taskforce
Living Guidelines https://covid19evidence.net.au/ for definitions of respiratory support requirements.
[Question ID: 43773]

- ◯ Not hospitalised, no limitations on activities *(jump to question **49**)*
- ◯ Not hospitalised, limitations on activities, home oxygen requirement, or both *(jump to question **49**)*
- ◯ Hospitalised, not requiring supplemental oxygen and no longer requiring ongoing medical care (used if hospitalisation was extended for infection-control reasons) *(jump to question **50**)*
- ◯ Hospitalised, not requiring supplemental oxygen but requiring ongoing medical care (COVID-19–related or other medical conditions) *(jump to question **50**)*
- ◯ Hospitalised, requiring supplemental oxygen via low flow oxygen devices *(jump to question **50**)*
- ◯ Hospitalised, requiring supplemental oxygen via High Flow Nasal Oxygen (HFNO) or other high flow oxygen devices *(jump to question **50**)*
- ◯ Hospitalised, on non-invasive ventilation (NIV) *(jump to question **50**)*
- ◯ Hospitalised, on invasive mechanical ventilation *(jump to question **51**)*
- ◯ Hospitalised, on Extracorporeal Membrane Oxygenation (ECMO) *(jump to question **51**)*
- ◯ Death *(jump to question **46**)*
- ◯ Other *(jump to question **45**)*

45. If other clinical status, please provide details [Question ID: 43774]

46. Date of death [Question ID: 43775]

47. Cause of death (as documented on death certificate) (if **COVID-19**, jump to question **51** ; if **Other**, jump to question **50**) [Question ID: 25201]

- ○ COVID-19
- ○ Other

48. If other, specify cause of death as per death certificate [Question ID: 25202]

49. *Specify the total hospital length of stay (LOS) in days [Question ID: 43776]

50. *Did the patient require intensive care? (if **Yes**, jump to question **51** ; if **No**, jump to question **52**) [Question ID: 43786]

- O Yes
- O No

51. Please specify the ICU LOS in days (numeric field) [Question ID: 44452]

Section G. Additional Information

52. Optional: please include any other information relevant to this report if not captured elsewhere

E.g. consider including:

- requirements and duration of intubation or ECMO
- scores on admission to and discharge from ICU such as SOFA or APACHE 2 etc.
- development of respiratory failure
- development of multiorgan failure

[Question ID: 43778]

Submission

- **You are now ready to submit the Tocilizumab IPU Adverse Events and Clinical Outcomes Report data.**
- **Please ensure you have completed all the questions marked with an asterisk*.**
- **Your local DTC will contact you if any further information is required.**

Thank you for your contribution.