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

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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).**
- **Completion of this report may take approximately 15 - 20 minutes.**

A response to each applicable question should be provided.

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_DATE) [Question ID: 25150]

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? (if **Yes**, jump to question **9** ; if **No**, jump to question **5**) [Question ID: 25151]

- O Yes
- O No

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 (if **Haematologist**, jump to question **9** ; if **Immunologist**, jump to question **9** ; if **Infectious Diseases Physician**, jump to question **9** ; if **Intensivist**, jump to question **9** ; if **Respiratory Physician**, jump to question **9** ; if **Other, please specify**, jump to question **8**) [Question ID: 25155]

- O Haematologist
- O Immunologist
- O Infectious Diseases Physician

- ☐ Intensivist
- ☐ Respiratory Physician
- ☐ Other, please specify

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

Section B. Patient Demographics

9. *Patient's full name [Question ID: 25157]

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

11. *Patient's Date of Birth (date format: dd/mm/yyyy) [Question ID: 25159]

12. *What date was the patient admitted? (date format: dd/mm/yyyy) [Question ID: 25414]

Section C. Tocilizumab Details

13. *What date was tocilizumab commenced? (date format: dd/mm/yyyy) [Question ID: 25160]

14. *Actual dosing (i.e. dose, frequency and duration administered) (if **8 mg/kg (maximum 800 mg) infused intravenously over 60 minutes for ONE single dose**, jump to question **16** ; if **8 mg/kg (maximum 800 mg) infused intravenously over 60 minutes for TWO doses**, jump to question **16** ; if **Other (please provide details in next question)**, jump to question **15**) [Question ID: 25516]

- O 8 mg/kg (maximum 800 mg) infused intravenously over 60 minutes for ONE single dose
- O 8 mg/kg (maximum 800 mg) infused intravenously over 60 minutes for TWO doses
- O Other (please provide details in next question)

15. If other, please specify dosing (i.e. dose, frequency, duration and reason) [Question ID: 25519]

16. *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
- 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: 25163]

Section D. Therapy Following Tocilizumab IPU Approval

17. *Was the patient acutely commenced on any of the listed therapies below during hospitalisation with COVID-19?

- Antiviral therapy
- Corticosteroid (not topical)
- Immunomodulator
- Antibacterial therapy
- Antithrombotic therapy
- Convalescent plasma
- Hyperimmune immunoglobulin
- Other therapy (specify in next question)

(if **Yes**, jump to question **18** ; if **No**, jump to question **19**) [Question ID: 25164]

O Yes

O No

18. Provide details of relevant therapies identified in question 17, including if it was part of a clinical trial [Question ID: 25165]

19. *Please select if the patient was commenced on any of the following medicines during hospitalisation with COVID-19 (more than one answer may be selected) [Question ID: 25166]

☐ No, the patient was not commenced on any of the listed medicines below

☐ ACE inhibitor

☐ Sartan

☐ Statin

20. *List any additional medications that were prescribed to the patient since the IPU approval (if not already identified elsewhere; use N/A if no additional medications) [Question ID: 25167]

21. *Did any potential or actual drug interactions impact the management of COVID-19 in this patient? (if **No relevant drug interactions**, jump to question **23** ; if **Yes, interaction(s) involving tocilizumab**, jump to question **22** ; if **Yes, interaction(s) involving other COVID-19 therapies**, jump to question **22** ; if **Yes, interaction(s) involving tocilizumab AND other COVID-19 therapies**, jump to question **22**) [Question ID: 25168]

O No relevant drug interactions

O Yes, interaction(s) involving tocilizumab

O Yes, interaction(s) involving other COVID-19 therapies

O Yes, interaction(s) involving tocilizumab AND other COVID-19 therapies

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

Section E. Possible or Likely Adverse Effects Due to Tocilizumab

23. *Did the patient experience any adverse effects (possible or likely) due to tocilizumab use? (if **Yes**, jump to question **24** ; if **No**, jump to question **47**) [Question ID: 25171]

O Yes

O No

24. Select the adverse effects, which were possible or likely due to tocilizumab use (more than one answer may be selected) [Question ID: 25173]

☐ 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

☐ Secondary opportunistic infection, out of keeping with clinical disease

☐ Hepatotoxicity - increase in LFTs = 5 times upper limit of normal

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

☐ 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

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

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

O Possibly

O Likely

O Don't know

27. 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]

28. What was the severity of the adverse effect? (if **Mild, no treatment required**, jump to question **30** ; if **Moderate to Severe, treatment required**, jump to question **29** ; if **Life-threatening**, jump to question **29** ; if **Don't know, no treatment required**, jump to question **30**) [Question ID: 25178]

O Mild, no treatment required

O Moderate to Severe, treatment required

O Life-threatening

O Don't know, no treatment required

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

30. Has the patient recovered from the adverse effect? (if **Yes**, jump to question **31** ; if **No**, jump to question **32** ; if **Don't know**, jump to question **32**) [Question ID: 25179]

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

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

32. Did the adverse effect prolong the hospitalisation? [Question ID: 25181]

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

33. 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]

34. Do you have a second adverse effect to provide information about? (if **Yes**, jump to question **35** ; if **No**, jump to question **46**) [Question ID: 25183]

- O Yes
- O No

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

Second adverse effect

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

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

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

37. 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]

38. What was the severity of the adverse effect? (if **Mild, no treatment required**, jump to question **40** ; if **Moderate to Severe, treatment required**, jump to question **39** ; if **Life-threatening**, jump to question **39** ; if **Don't know, no treatment required**, jump to question **40**) [Question ID: 25186]

- O Mild, no treatment required
- O Moderate to Severe, treatment required
- O Life-threatening
- O Don't know, no treatment required

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

40. Has the patient recovered from the adverse effect? (if **Yes**, jump to question **41** ; if **No**, jump to question **42** ; if **Don't know**, jump to question **42**) [Question ID: 25187]

- O Yes
- O No

O Don't know

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

42. Did the adverse effect prolong the hospitalisation? [Question ID: 25189]

O Yes

O No

O Don't know

43. 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]

44. Were any other adverse effects due to tocilizumab (possible or likely) experienced by the patient? (if **Yes**, jump to question **45** ; if **No**, jump to question **46**) [Question ID: 25192]

O Yes

O No

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

Additional adverse drug effects (three or more)

45. 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]

- Treatment given 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 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: 25193]

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

46. 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

47. *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.
(if **Not hospitalised, no limitations on activities**, jump to question **51** ; if **Not hospitalised, limitations on activities, home oxygen requirement, or both**, jump to question **51** ; if **Hospitalised, not requiring supplemental oxygen and no longer requiring ongoing medical care (used if hospitalisation was extended for infection-control reasons)**, jump to question **52** ; if **Hospitalised, not requiring supplemental oxygen but requiring ongoing medical care (COVID-19–related or other medical conditions)**, jump to question **52** ; if **Hospitalised, requiring supplemental oxygen via low flow oxygen devices**, jump to question **52** ; if **Hospitalised, requiring supplemental oxygen via High Flow Nasal Oxygen (HFNO) or other high flow oxygen devices**, jump to question **52** ; if **Hospitalised, on non-invasive ventilation (NIV)**, jump to question **52** ; if **Hospitalised, on invasive mechanical ventilation**, jump to question **52** ; if **Hospitalised, on Extracorporeal Membrane Oxygenation (ECMO)**, jump to question **52** ; if **Death**, jump to question **48**) [Question ID: 25198]

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

48. Date of death (date format: dd/mm/yyyy) [Question ID: 25200]

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

- O COVID-19
- O Other

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

51. *Specify the total hospital length of stay (LOS) in days (numeric field) [Question ID: 25203]

52. *Did the patient require intensive care? (if **Yes**, jump to question **53** ; if **No**, jump to question **54**) [Question ID: 25204]

- O Yes
- O No

53. Specify the ICU LOS in days (numeric field) [Question ID: 25205]

54. *Select if the patient experienced any of the following during the course of the COVID-19 disease (more than one answer may be selected) [Question ID: 25207]

☐ Respiratory failure

☐ Multiorgan failure

Section G. Additional Information

55. Optional: please include any other information relevant to this report if not captured elsewhere
(Consider including information such as requirements for and duration of intubation and ECMO, SOFA score, APACHE 2 score on admission to ICU where applicable)
[Question ID: 25208]

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.