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

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Tocilizumab IPU application for applicant (prescriber) completion

Please read before you begin your IPU application for tocilizumab:

- **It is recommended that applicants familiarise themselves with the questions and information required in this online IPU form BEFORE proceeding (scroll down to view all questions).**
- **The application form can only be completed in one session.**
    - **You cannot save, close and come back to the IPU form at a later time (if you are called away, the form will remain open unless your browser is closed).**
- **Completion of the IPU form takes approximately 10 - 20 minutes.**

A response to each question should be provided. Failure to respond may result in a delay in the approval of this application.

1. ***Enter an 'IPU application code' unique to this patient**

Suggest follow this template Toci_LHD_MRN_DATE
e.g. *Toci_WSLHD_0123456_15072020*

[Question ID: 25089]

Section A. IPU Applicant's (i.e. Prescriber's) Details

2. *Applicant's full name [Question ID: 25090]

3. *Applicant's email address [Question ID: 25091]

4. *Applicant's contact phone number (extension and/or mobile number) [Question ID: 25092]

5. *Applicant's specialty
(if Other, please specify) (if **Immunologist**, jump to question **7** ; if **Haematologist**, jump to question **7** ; if **Infectious Diseases Physician**, jump to question **7** ; if **Intensivist**, jump to question **7** ; if **Respiratory Physician**, jump to question **7** ; if **Other, please specify**, jump to question **6**) [Question ID: 25093]

- O Immunologist
- O Haematologist
- O Infectious Diseases Physician
- O Intensivist
- O Respiratory Physician
- O Other, please specify

6. If other specialty, please specify [Question ID: 25094]

7. *Have you consulted another specialty clinician for a second opinion? (if **Yes**, jump to question **8** ; if **No**, jump to question **9**) [Question ID: 25095]

- O Yes
- O No

8. *Please provide name and specialty of the clinician who provided the second opinion. [Question ID: 25096]

9. If no to question 7, provide reason [Question ID: 25097]

10. *Have you obtained approval from your Head of Department? [Question ID: 25098]

- O Yes
- O No

11. *Do you have any conflicts of interest regarding this application to declare?

Tocilizumab (Actemra) is manufactured by Roche Products Pty Limited.
Financial or other interests resulting from contact with pharmaceutical companies, which may have a bearing on this submission may include:

- Gifts
- Industry paid food/refreshments
- Travel expenses
- Honoraria
- Samples
- Research support
- Other types of support

(if **Yes**, jump to question **12** ; if **No**, jump to question **13**) [Question ID: 25099]

- O Yes
- O No

12. Please describe conflict of interest [Question ID: 25100]

13. *Name of LHD/SHN [Question ID: 25101]

- O Central Coast LHD
- O Far West LHD
- O Hunter New England LHD
- O Illawarra Shoalhaven LHD
- O Justice Health and Forensic Mental Health SHN
- O Mid North Coast LHD
- O Murrumbidgee LHD
- O Nepean Blue Mountains LHD
- O Northern NSW LHD
- O Northern Sydney LHD
- O South Eastern Sydney LHD
- O South Western Sydney LHD
- O Southern NSW LHD
- O St Vincent's Health Network SHN
- O Sydney LHD
- O Sydney Children's Hospitals Network SHN
- O Western NSW LHD
- O Western Sydney LHD

Section B. Patient Demographics

14. *Patient's full name [Question ID: 25104]

15. *Patient's MRN [Question ID: 25105]

16. *Patient's Date of Birth (date format: dd/mm/yyyy) [Question ID: 25106]

17. *Patient's Gender [Question ID: 25107]

- O Male
- O Female
- O Other

18. *Hospital name [Question ID: 25108]

19. *Patient location (if **ICU**, jump to question **21** ; if **Non-ICU**, jump to question **20**) [Question ID: 25109]

- O ICU
- O Non-ICU

20. If non-ICU, specify ward (name/number and type, e.g. general, COVID-19, HDU, other) [Question ID: 25110]

Section C. COVID-19 Infection Status and Severity of Illness

21. *Date of symptom onset (date format: dd/mm/yyyy) [Question ID: 25111]

22. *COVID-19 Test Result [Question ID: 25112]

- O Positive
- O Pending
- O Indeterminate

23. *Current severity of Illness.

Definition of disease severity from the National COVID-19 Clinical Evidence Taskforce Living Guidelines https://covid19evidence.net.au/	
Severe illness	Patients meeting any of the following criteria: • respiratory rate ≥ 30 breaths/min • oxygen saturation ≤ 92% at a rest state • arterial partial pressure of oxygen (PaO2)/ inspired oxygen fraction (FiO2) ≤ 300
Critical illness	Patient meeting any of the following criteria: Respiratory failure • Occurrence of severe respiratory failure (PaO2/FiO2 ratio < 200), respiratory distress or acute respiratory distress syndrome (ARDS). This includes patients deteriorating despite advanced forms of respiratory support (NIV, HFNO) OR patients requiring mechanical ventilation. OR other signs of significant deterioration • hypotension or shock • impairment of consciousness • other organ failure

The patient is: (if **Severely ill**, jump to question **25** ; if **Critically ill**, jump to question **25** ; if **Other**, jump to question **24**) [Question ID: 25113]

- O Severely ill
- O Critically ill
- O Other

24. If other severity of illness, provide details [Question ID: 25114]

25. *Current respiratory support requirements

Based on National COVID-19 Clinical Evidence Taskforce
Living Guidelines definitions for respiratory support. (https://covid19evidence.net.au/) [Question ID: 25115]

- O Hospitalised, not requiring supplemental oxygen
- 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)

26. *Please select any pre-existing poor prognostic factors for COVID-19 (more than one answer may be selected) [Question ID: 25132]

- ☐ Age equal to or greater than 65 years
- ☐ Current smoker
- ☐ BMI equal to or greater than 30 kg/m2 and less than 40 kg/m2
- ☐ BMI equal to or greater than 40 kg/m2
- ☐ Hypertension
- ☐ Hyperlipidaemia
- ☐ Other cardiovascular disease (please specify in next question)
- ☐ Cerebrovascular disease
- ☐ Diabetes
- ☐ Chronic respiratory disease (please specify in next question)
- ☐ Chronic kidney disease (eGFR < 60 mL/min/1.73 m2)
- ☐ Hepatic impairment
- ☐ Cancer
- ☐ Other (please provide details in next question)
- ☐ No poor prognostic factors for COVID-19 identified

27. Please provide more specific details of other cardiovascular disease, chronic respiratory disease, cancer or other factors, if relevant. [Question ID: 25133]

Section D. Reason for IPU application

N.B. You may attach supporting documents to this application e.g. further evidence (if required) in the IPU submission notification email sent to the DTC.

28. *Select any clinical trials involving tocilizumab at your hospital (more than one answer may apply) [Question ID: 25102]

- ☐ REMAP-CAP
- ☐ ASCOT
- ☐ Other (provide details in next question)
- ☐ No relevant clinical trials involving tocilizumab
- ☐ Don't know

29. If other, provide the name(s) of any relevant trial(s) involving tocilizumab below (put N/A if question not applicable) [Question ID: 25103]

30. *Please select reason for IPU application (if **Hospital not participating in relevant clinical trial**, jump to question **34** ; if **Patient not eligible for relevant clinical trial (select reason for exclusion in follow up question)**, jump to question **32** ; if **Other (please provide details)**, jump to question **31**) [Question ID: 25116]

- ○ Hospital not participating in relevant clinical trial
- ○ Patient not eligible for relevant clinical trial (select reason for exclusion in follow up question)
- ○ Other (please provide details)

31. If other reason for IPU application, please provide details [Question ID: 25117]

32. Reasons for exclusion from clinical trial (more than one answer may be selected) [Question ID: 25118]

☐ Age

☐ Renal impairment

☐ Hepatic impairment

☐ Known or suspected pregnancy

☐ Platelet count

☐ Neutropenia

☐ COVID-19 severity

☐ Inpatient location

☐ Time in ICU

☐ Respiratory support requirements

☐ Current or previous use of one or more of the trial drugs during current hospitalisation or is on long-term therapy with the trial drugs prior to current hospitalisation

☐ Use or proposed use of medications that are contraindicated with one or more of the trial drugs

☐ Currently on other investigational agents with targeted immunomodulatory effects

☐ Known allergy or hypersensitivity to one or more of the trial drugs but not to tocilizumab

☐ Treating team deems enrolment in the study is not in the best interests of the patient

☐ Previous participation in the trial

☐ Pre-existing medical conditions (provide details in next question)

☐ Other (please provide details in next question)

33. If other pre-existing medical conditions or any other reason(s) excluded the patient from an applicable clinical trial, provide details [Question ID: 25119]

Section E. Tocilizumab Dosing Information

34. *Proposed dose, frequency and duration (if **8 mg/kg (maximum 800 mg) infused intravenously over 60 minutes for ONE single dose**, jump to question **36** ; if **8 mg/kg (maximum 800 mg) infused intravenously over 60 minutes for TWO doses**, jump to question **36** ; if **Other (please provide details in next question)**, jump to question **35**) [Question ID: 25120]

- 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)

35. If other, please specify proposed dose, frequency, duration and reason [Question ID: 25121]

36. *Patient weight in kg (numeric field) [Question ID: 25122]

37. *Enter (in mg) the calculated dose that you propose to use (numeric field) [Question ID: 25123]

Section F. Contraindications, Precautions

38. *Contraindications for tocilizumab use include:

- Hypersensitivity including anaphylaxis to tocilizumab
- Active hepatic disease
- A history of active diverticulitis (due to risk of GI perforation)

(Refer to tocilizumab drug guideline and the product information for detailed contraindication information)

Are any contraindications present? (if **No contraindications exist**, jump to question **40** ; if **Contraindications exist, please describe below**, jump to question **39**) [Question ID: 25124]

- O No contraindications exist
- O Contraindications exist, please describe below

39. Describe contraindications [Question ID: 25125]

40. *Please select the following precautions for tocilizumab use in COVID-19 if they are present (more than one answer may be selected) [Question ID: 25126]

☐ Sepsis or infections from non-COVID-19 pathogen (please provide details in next question)

☐ Hepatic impairment including abnormal liver enzymes (transaminases 3-5 times the upper limit of normal)

☐ Absolute neutrophil count < 2 x 10^9/L

☐ Platelet count < 100 x 10^9/L

☐ Severe haematological disorder

☐ Immunosuppression

☐ Previous history of intestinal ulceration

☐ Known or suspected pregnancy

☐ Other (please provide details in next question)

☐ No precautions present

41. If other precaution(s) or sepsis/infections from non-COVID-19 pathogen selected, provide details [Question ID: 25127]

42. *A check for drug interactions is required prior to prescribing tocilizumab

Potential drug interactions have not been investigated in patients with COVID-19. It is prudent to minimise the concurrent use of any nonessential medications whenever possible. Consider the following:

- **Tocilizumab has no inhibitory or inducing effects on cytochromes. However, patients infected with COVID-19 may experience IL-6 elevation, shown to suppress activity of drug metabolising enzymes, namely CYP3A4, but also others. Tocilizumab will normalise cytochrome activity (via inhibition of IL-6).**
- **The effect of tocilizumab on CYP450 enzymes may be clinically relevant for CYP450 substrates. Consider whether medication doses may require adjustment during hospitalisation. (Further information available from University of Liverpool interactions checker).**

Please select if the patient is prescribed/is likely to be prescribed any of the medicines which may potentially interact with tocilizumab (more than one answer may be selected) [Question ID: 25128]

- ☐ No drug interactions present
- ☐ Warfarin
- ☐ Antiepileptics e.g. carbamazepine, phenytoin
- ☐ Benzodiazepines
- ☐ Opioids, e.g. fentanyl, oxycodone
- ☐ Amiodarone
- ☐ Apixaban, clopidogrel, prasugrel, rivaroxaban, ticagrelor
- ☐ Hydroxychloroquine
- ☐ Interferon beta
- ☐ Other (please provide details in next question)

43. If other drug interaction(s), provide details [Question ID: 25129]

44. *Is the patient on any pre-existing medicines with haematological or immunosuppressive effects? (if **Yes**, jump to question **45** ; if **No**, jump to question **46**) [Question ID: 25130]

- ○ Yes
- ○ No

45. Please specify medicines [Question ID: 25131]

Section G. Other Proposed or Concurrent Therapy

46. *Please select if the following antivirals have been prescribed or there is a current plan to prescribe (more than one answer may be selected) [Question ID: 25134]

- ☐ No antivirals
- ☐ Lopinavir/ritonavir
- ☐ Hydroxychloroquine
- ☐ Remdesivir
- ☐ Oseltamivir
- ☐ Other (please provide details in next question)

47. If other antiviral, provide details [Question ID: 25135]

48. *Please select if the any of the following corticosteroids (not topical) have been prescribed acutely or there is a current plan to prescribe (if **No corticosteroids**, jump to question **50** ; if **Dexamethasone**, jump to question **49** ; if **Hydrocortisone**, jump to question **49** ; if **Methylprednisolone**, jump to question **49** ; if **Prednisone/Prednisolone**, jump to question **49**) [Question ID: 25136]

- O No corticosteroids
- O Dexamethasone
- O Hydrocortisone
- O Methylprednisolone
- O Prednisone/Prednisolone

49. If acute use or planned use of corticosteroid, provide dose and route details [Question ID: 25137]

50. *Please select if any of the following immunomodulators have been prescribed acutely or there is a current plan to prescribe (if **No other current or planned immunomodulator**, jump to question **52** ; if **Anakinra**, jump to question **52** ; if **Other (please provide details in next question)**, jump to question **51**) [Question ID: 25138]

- O No other current or planned immunomodulator
- O Anakinra
- O Other (please provide details in next question)

51. If other immunomodulator, provide details [Question ID: 25139]

52. *Please select if antibacterial therapy has been prescribed or there is a current plan to prescribe (more than one answer may be selected) [Question ID: 25140]

- ☐ No antibacterial therapy current or planned
- ☐ Amoxicillin with clavulanic acid
- ☐ Amoxicillin
- ☐ Azithromycin
- ☐ Benzylpenicillin
- ☐ Ceftriaxone
- ☐ Doxycycline
- ☐ Gentamicin
- ☐ Piperacillin/tazobactam
- ☐ Other (please provide details in next question)

53. If other antibacterial therapy, provide details [Question ID: 25141]

54. *Please select if antithrombotic therapy has been prescribed or there is a current plan to prescribe (if **No antithrombotic therapy current or planned**, jump to question **56** ; if **Therapeutic dose VTE therapy (LMWH or unfractionated heparin)**, jump to question **56** ; if **Prophylactic dose VTE therapy (LMWH or unfractionated heparin)**, jump to question **56** ; if **Other (if other antithrombotic regimen current or planned, please provide details in next question)**, jump to question **55**) [Question ID: 25142]

- ○ No antithrombotic therapy current or planned
- ○ Therapeutic dose VTE therapy (LMWH or unfractionated heparin)
- ○ Prophylactic dose VTE therapy (LMWH or unfractionated heparin)
- ○ Other (if other antithrombotic regimen current or planned, please provide details in next question)

55. If other antithrombotic regimen current or planned, provide details [Question ID: 25143]

56. *Please select if any of the following therapies have been prescribed acutely or there is a current plan to prescribe [Question ID: 25466]

- ☐ No current or planned treatment with the listed therapies below
- ☐ Convalescent plasma
- ☐ Hyperimmune immunoglobulin

57. *Please select if any of the following medicines have been prescribed or there is a current plan to prescribe (more than one answer may be selected) [Question ID: 25144]

- ☐ No current or planned treatment with the listed medicines below
- ☐ NSAID, chronic use
- ☐ Corticosteroid, chronic use
- ☐ Immunosuppressant, chronic use
- ☐ ACE inhibitor, chronic use
- ☐ ACE inhibitor, planned use
- ☐ ACE inhibitor, acute use
- ☐ Sartan, chronic use
- ☐ Sartan, planned use
- ☐ Sartan, acute use
- ☐ Statin, chronic use
- ☐ Statin, planned use
- ☐ Statin, acute use

Section H. Outcome reporting

58. *I agree to report any potential adverse events and other clinical outcomes of this individual patient use [Question ID: 25145]

- ○ Yes
- ○ No

Section I. Additional Information

59. *Has informed patient consent been obtained and documented in the medical record? [Question ID: 25146]

- O Yes
- O No
- O Pending

60. Optional: please include any other information relevant to this IPU application if not captured elsewhere [Question ID: 25147]

Submission

Before clicking 'Submit and Close', please ensure you have responded to all the questions marked with an asterisk*.

You must notify the DTC via email of your submission. Click on the relevant hyperlinked DTC contact email below to open an email window to write the submission email.

DTC email: _____
DTC phone number: _____

Include in the email the following details at a minimum (suggest copy and paste and complete the template below):

Dear DTC,

An IPU application for Tocilizumab has been submitted for *[patient name, MRN]* for DTC review.
IPU application code: *Insert the unique IPU application code**
*Toci [LHD] [MRN] [DATE] *(code entered at beginning of application form).*
The urgency for DTC review of the IPU application is: *(ASAP, <24 hours, 24-72 hours, other (provide detail))*

Kind regards,
Applicant

Your local DTC will contact you with an outcome of your application. If the IPU is approved, the DTC will provide you with a hyperlink to the 'Tocilizumab Adverse Event and Clinical Outcome Reporting Form' for completion within 21 days of tocilizumab commencement.

Thank you