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

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The information on page 1 of this form do not apply to the manual completion of this PDF form.

Remdesivir
Adverse Events and Clinical Outcomes Report Form
for prescriber (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 <u>cannot</u> 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 remdesivir cessation, discharge or death.

1. *Enter a 'code' unique to this patient

(use the same code that was selected in the prescribing declaration form / IPU submission with the suggested template Remdesivir_LHD_MRN_DATEofADMISSION or refer to the email from the DTC for the unique code)
[Question ID: 38377]

2. *What is today's date? (date format: dd/mm/yyyy) [Question ID: 26939]

Section A. Clinician's details

3. *Full name of clinician providing this report [Question ID: 35858]

4. *Are you the same clinician who made the original remdesivir prescribing declaration / IPU? [Question ID: 38753]

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

5. Clinician's email address [Question ID: 26944]

6. Clinician's contact number (pager and/or extension and/or mobile number) [Question ID: 38749]

7. Clinician's specialty [Question ID: 39538]

- O Infectious Diseases Physician (jump to question **9**)
- O Intensivist (jump to question **9**)
- O Respiratory Physician (jump to question **9**)
- O Emergency Medicine Physician (jump to question **9**)
- O Other, please specify (jump to question **8**)

8. If other specialty, please specify [Question ID: 26947]

Section B. Patient Demographics

9. *Patient's MRN [Question ID: 26951]

10. *What date was the patient admitted to hospital? (date format: dd/mm/yyyy) [Question ID: 38751]

11. *Please select any pre-existing poor prognostic factors for COVID-19 (more than one answer may be selected) [Question ID: 35871]

- ☐ Preterm birth (provide details in next question)
- ☐ Age = or > 65 years
- ☐ Frailty
- ☐ 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 (please specify in next question)
- ☐ Diabetes
- ☐ Chronic respiratory disease or use of respiratory support prior to COVID-19 (please specify in next question)
- ☐ Chronic kidney disease (eGFR < 60 mL/min/1.73 m2)
- ☐ Hepatic impairment
- ☐ Cancer
- ☐ Major congenital malformations influencing outcomes in acute illness (please provide details in next question).
- ☐ Other (please provide details in next question)
- ☐ No poor prognostic factors for COVID-19 identified

12. Please provide more specific details of preterm birth, other cardiovascular/cerebrovascular disease, chronic respiratory disease, cancer, congenital malformations or other factors, if relevant. [Question ID: 35872]

Section C. Remdesivir Details

13. *What date was remdesivir commenced? (date format: dd/mm/yyyy) [Question ID: 26954]

14. *Actual duration of remdesivir treatment [Question ID: 38754]

- ◯ 5 days (jump to question **16**)
- ◯ 10 days (jump to question **16**)
- ◯ Other (please provide details in next question) (jump to question **15**)

15. If other, please specify dosing duration and reason [Question ID: 38378]

16. *If the actual dosing was different to that initially proposed, 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**
- **contraindication identified**
- **adverse drug effect experienced (identify here and provide details in section E)**
- **death occurred**

[Question ID: 35897]

Section D. Concomitant Therapy

17. *Select if the patient was acutely commenced on any of the listed therapies below during hospitalisation with COVID-19 (more than one answer may be selected) [Question ID: 38981]

- ☐ Other antiviral therapy
- ☐ Corticosteroid (not topical)
- ☐ Immunomodulator
- ☐ 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

18. Provide details of relevant therapies identified in question 19, including if it was part of a clinical trial [Question ID: 26959]

19. *Did any potential or actual drug interactions impact the management of COVID-19 in this patient? (e.g. required change in choice of therapies / dose changes) [Question ID: 38759]

- ○ No relevant drug interactions identified (jump to question **21**)
- ○ Yes, interaction(s) involving remdesivir (jump to question **20**)
- ○ Yes, interaction(s) involving other relevant COVID-19 therapies (jump to question **20**)
- ○ Yes, interaction(s) involving remdesivir AND other COVID-19 therapies (jump to question **20**)

20. Provide details of drug interaction(s) [Question ID: 26963]

Section E. Possible or Likely Adverse Effects Due to Remdesivir

21. *Did the patient experience any adverse effects (possible or likely) due to remdesivir use? (if **Yes**, jump to question **22** ; if **No**, jump to question **45**) [Question ID: 38760]

- O Yes
- O No

22. Select the adverse effects, which were possible or likely due to remdesivir use (more than one answer may be selected) [Question ID: 38755]

- ☐ Increase(s) in LFTs
- ☐ Possible allergic reaction, including anaphylactic reactions and angioedema
- ☐ Infusion-related reactions (within 24 hours of IV infusion; including but not limited to hypotension, nausea, vomiting, diaphoresis and shivering)
- ☐ Gastrointestinal symptoms not related to infusion reaction (e.g. nausea, vomiting, diarrhoea)
- ☐ Headache
- ☐ Rash
- ☐ Death
- ☐ Other (please provide details in next section)

You are required to provide details for each adverse effect identified in question 22. If there are more than TWO adverse effects, a free text field to provide details of additional adverse effects follows.

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

First adverse effect

23. What was the adverse effect?
(Name the adverse effect only, further details to be provided below) [Question ID: 26966]

24. What was the likelihood that this adverse effect was due to remdesivir use? [Question ID: 38756]

- O Possible
- O Likely
- O Don't know

25. What was the timing of onset of the adverse effect after the initial remdesivir dose was administered (in hours/minutes as applicable)? [Question ID: 26967]

26. What was the severity of the adverse effect? [Question ID: 38761]

- O Mild, no treatment required (jump to question **28**)
- O Moderate to Severe, treatment required (jump to question **27**)
- O Life-threatening (jump to question **27**)
- O Don’t know, no treatment required (jump to question **28**)

27. Provide details of administered treatment for adverse effect including relevant laboratory results and/or diagnostic procedures [Question ID: 26970]

28. Has the patient recovered from the adverse effect? [Question ID: 38762]

- O Yes (jump to question **29**)
- O No (jump to question **30**)
- O Don't know (jump to question **30**)

29. How long did it take before the patient recovered from the adverse effect (minutes/hours/days)? [Question ID: 26972]

30. Did the adverse effect prolong the hospitalisation or cause death? [Question ID: 26973]

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

31. 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: 26974]

32. Do you have a second adverse effect to provide information about? [Question ID: 38763]

- O Yes (jump to question **33**)
- O No (jump to question **44**)

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

Second adverse effect

33. What was the adverse effect?
(Name the adverse effect only, further details to be provided below) [Question ID: 26976]

34. What was the likelihood that this adverse effect was due to remdesivir use? [Question ID: 38757]

- O Possible
- O Likely
- O Don't know

35. What was the timing of onset of the adverse effect after the initial remdesivir dose was administered (in hours/minutes as applicable)? [Question ID: 26978]

36. What was the severity of the adverse effect? [Question ID: 38764]

- O Mild, no treatment required (jump to question **38**)
- O Moderate to Severe, treatment required (jump to question **37**)
- O Life-threatening (jump to question **37**)
- O Don't know, no treatment required (jump to question **38**)

37. Provide details of administered treatment for adverse effect including relevant laboratory results and/or diagnostic procedures [Question ID: 26980]

38. Has the patient recovered from the adverse effect? [Question ID: 38765]

- O Yes (jump to question **39**)
- O No (jump to question **40**)
- O Don't know (jump to question **40**)

39. How long did it take before the patient recovered from the adverse effect (minutes/hours/days)? [Question ID: 26982]

40. Did the adverse effect prolong the hospitalisation or cause death? [Question ID: 26983]

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

41. 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: 26984]

42. Were any other adverse effects due to Remdesivir (possible or likely) experienced by the patient? [Question ID: 38766]

- O Yes (jump to question **43**)
- O No (jump to question **44**)

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

Additional adverse drug effects (three or more)

43. 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 remdesivir: [possible/ likely/ don't know]
- Timing of onset of the adverse effect after initial remdesivir 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 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: 38758]

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

44. *Were adverse effect(s) reported elsewhere? [Question ID: 26987]

- O No
- O Yes, reported to both the TGA/Gilead 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/Gilead
- O Not sure

Section F. Clinical Outcomes

45. *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 for

- Adults
- Neonates, children and adolescents

[Question ID: 38771]

- O Not hospitalised, no limitations on activities (jump to question **50**)
- O Not hospitalised, limitations on activities, home oxygen requirement, or both (jump to question **50**)
- O Hospitalised, not requiring supplemental oxygen and no longer requiring ongoing medical care (used if hospitalisation was extended for infection-control reasons) (jump to question **51**)
- O Hospitalised, not requiring supplemental oxygen but requiring ongoing medical care (COVID-19–related or other medical conditions) (jump to question **51**)
- O Hospitalised, requiring supplemental oxygen via low flow oxygen devices (jump to question **51**)
- O Hospitalised, requiring supplemental oxygen via High Flow Nasal Oxygen (HFNO) or other high flow oxygen devices (jump to question **51**)
- O Hospitalised, on non-invasive ventilation (NIV) (jump to question **51**)
- O Hospitalised, on invasive mechanical ventilation (jump to question **52**)
- O Hospitalised, on Extracorporeal Membrane Oxygenation (ECMO) (jump to question **52**)
- O Death (jump to question **47**)
- O Other (please provide details in next question) (jump to question **46**)

46. If other clinical status, please provide details [Question ID: 35883]

47. Date of death (date format: dd/mm/yyyy) [Question ID: 26990]

48. Cause of death (as documented on death certificate) (if **COVID-19**, jump to question **52** ; if **Other**, jump to question **49**) [Question ID: 38774]

- O COVID-19
- O Other

49. If other, specify cause of death as per death certificate [Question ID: 26992]

50. *Specify the total hospital length of stay (LOS) in days (numeric field) [Question ID: 26993]

51. *Did the patient require intensive care? (if **Yes**, jump to question **52** ; if **No**, jump to question **53**) [Question ID: 38775]

- O Yes
- O No

52. Specify the ICU/PICU/NICU LOS in days (numeric field) [Question ID: 39535]

Section G. Additional Information

53. 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: 38752]

Submission

- You are now ready to submit the Remdesivir 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.