38. Provide details of administered treatment for adverse effect including relevant laboratory results and/or diagnostic procedures

39. Has the patient recovered from the adverse effect?

- O Yes (jump to question **40**)
- O No (jump to question **41**)
- O Don't know (jump to question **41**)

40. How long did it take before the patient recovered from the adverse effect (minutes/hours/days)?

41. Did the adverse effect prolong the hospitalisation or cause death?

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

42. 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.)

43. Were any other adverse effects due to Remdesivir (possible or likely) experienced by the patient?

- O Yes (jump to question **44**)
- O No (jump to question **45**)

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

Additional adverse drug effects (three or more)

44. 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.)

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

45. *Were adverse effect(s) reported elsewhere?

- 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

46. *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

- ◯ Not hospitalised, no limitations on activities (jump to question **51**)
- ◯ Not hospitalised, limitations on activities, home oxygen requirement, or both (jump to question **51**)
- ◯ 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**)
- ◯ Hospitalised, not requiring supplemental oxygen but requiring ongoing medical care (COVID-19–related or other medical conditions) (jump to question **52**)
- ◯ Hospitalised, requiring supplemental oxygen via low flow oxygen devices (jump to question **52**)
- ◯ Hospitalised, requiring supplemental oxygen via High Flow Nasal Oxygen (HFNO) or other high flow oxygen devices (jump to question **52**)
- ◯ Hospitalised, on non-invasive ventilation (NIV) (jump to question **52**)
- ◯ Hospitalised, on invasive mechanical ventilation (jump to question **53**)
- ◯ Hospitalised, on Extracorporeal Membrane Oxygenation (ECMO) (jump to question **53**)
- ◯ Death (jump to question **48**)
- ◯ Other (please provide details in next question) (jump to question **47**)

47. If other clinical status, please provide details

48. Date of death (date format: dd/mm/yyyy)

49. Cause of death (as documented on death certificate)

- O COVID-19 (jump to question **51**)
- O Other (jump to question **50**)

50. If other, specify cause of death as per death certificate

51. *Specify the total hospital length of stay (LOS) in days (numeric field)

52. *Did the patient require intensive care?

- O Yes (jump to question **53**)
- O No (jump to question **54**)

53. Specify the ICU/PICU/NICU LOS in days (numeric field)

Section G. Additional Information

54. 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

55. What was the patient's COVID-19 vaccination status on admission?

- ◯ Not vaccinated against COVID-19 (questionnaire finished)
- ◯ Partially vaccinated, received part of the vaccination course (jump to question **56**)
- ◯ Fully vaccinated, however second vaccine dose was within 2 weeks of admission (jump to question **56**)
- ◯ Fully vaccinated, however, patient was immunosuppressed prior to admission (jump to question **56**)
- ◯ Fully vaccinated (jump to question **56**)
- ◯ Other (please provide details below) (jump to question **56**)

56. If known, provide details of:

- which vaccine they received,
- dates of any doses,
- details of immunosuppression if applicable

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.