Cardamon Guidance Document

AESI Completion Guidance

- This is a guidance document aimed at providing further instructions to sites about entering AESI information on the SAE form.
- **All other sections of the SAE form will be completed as normal**.

Section 2 (page 1 of report): Initial Report	
Type of report	Tick the "Adverse Event of Special Interest (AESI)" box
Section 4 (page 1 of report): Serious Events	
Event term	Use "Infections and infestations - Other, specify: COVID-19 "
Severity Grade	- Should be consistent with the description in CTCAE v4.03 (below), and verifiable via test results and/or information in the event summary. - Should reflect the grade at its maximum severity. - Amend in update reports if the event worsens. Grade 1: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated Grade 2: Moderate; minimal, local or non-invasive intervention indicated; limiting age appropriate instrumental ADL Grade 3: Severe or medically significant but not immediately life threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self-care ADL Grade 4: Life-threatening consequences; urgent intervention indicated

	Grade 5: Death
Date of event onset	Use date of the first antigen testing that showed a positive antigen result.
Date of event resolution	The date the event resolved (e.g. completely resolved or returned to baseline), or resolved with sequelae. If, at the time of the report, the event had not resolved or outcome is unknown, leave blank. For events which are not the cause or significant contributor to death, the date should be left blank (see also Outcome). Use the date of negative antigen testing.
Seriousness criteria	Include all seriousness codes applicable to the AESI. - Death should only be selected as a seriousness criteria if the death of the patient is possibly related to the event i.e. the event was the cause or a significant contributor of death. Please note that in this case, outcome is fatal and severity grade should be marked as 5 (see also - severity).
Outcome of event	- state outcome of COVID-19 event rather than antigen testing. This data element captures the latest outcome of the event at the time of the report. Fatal should only be selected as an outcome if the event was the cause or significant contributor to death. Where the death is unrelated to the reaction/event, please select “Not resolved”. Death (related or unrelated to the event) is captured in the “Date and cause of death” section
Investigator’s assessment of causal relationship to event	Provide causal relationship between each event and each trial treatment (related/not related). This must be performed by the PI or a member of staff at the site formally delegated this responsibility.
Date and cause of death	If it is known that the patient has died at the time of the report, capture cause and date of death here, whether or not the death is related to the event. Indicate if an autopsy report is available.
Date of hospitalisation and date of discharge	If event required a new hospitalisation, please include the dates of hospitalisation. If the event caused prolongation of hospitalisation, include the date of the initial admission (rather than the date the admission was prolonged). Enter the date of discharge if applicable.
If an event is medically significant, specify why	The ”other medically significant” box should be ticked for AESIs (as well as any other boxes if seriousness criteria met).
Section 6 (page 3 of report): Any relevant tests/laboratory data applicable to this SAE? (tick yes and fill out or no and leave blank)	
Provide information on any relevant tests/laboratory data AND the following if done: • COVID-19 PCR swab test (initial and any follow-up swabs if applicable) • COVID-19 antibody test	

- Neutrophil count at COVID-19 diagnosis

If any of the above tests were not done, please state this in the narrative.

Section 7 (page 3 of report): Any non-serious events related to this case? (tick yes and fill out or no and leave blank)

Provide details of any symptoms experienced by the patient and confirm if the patient has experienced fever, new/continuous cough, breathlessness, anosmia.

Ensure that the severity grades and start and resolution dates are provided.

Section 10 (page 3 of report): Treatment of SAE (tick yes and fill out or no and leave blank)

Provide details of any treatment the patient received to treat COVID-19 and confirm if oxygen and ventilatory support were required. Please include the dose, frequency, route and start and stop dates of all treatment, and confirm if the patient has participated in any COVID-19 trials. If patient has participated in any COVID-19 trials, please specify the name of the trial and the treatment received.

Section 12 (page 4 of report): Case narrative

- Please provide a summary of relevant information, in chronological order of patient's experience:
    - Include/further explain relevant information for the case.
    - Include details of how the patient presented, the clinical course, source data to verify the event name, grade and onset date if this is not already captured in the test results section, therapeutic measures taken, outcome in the patient.
    - If outcome is fatal, relevant details (autopsy or post-mortem findings)
- Rationale for causality assessment.
- In follow-ups, new information should be clearly identified.

Note: Do not use acronyms and abbreviations

Ensure the following is covered in the narrative:

- The start date of the most recent cycle.
- If the event was complicated by Acute Kidney Injury.
- If the event was complicated by a Venous Thromboembolic Event.
- If the patient required ITU admission? If yes, please provide date of admission and discharge.
- If the patient recovered.
- If applicable, the date of when the maintenance chemotherapy restarted.