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| **SERIOUS ADVERSE EVENT REPORT**  ***\*\* DO NOT SEND IDENTIFIABLE DATA WITH THIS FORM \*\****  *All serious adverse events are to be reported to ITCC using this form within 24 hours of awareness of the event, irrespective of and in addition to any reporting requirements to the approving HREC* | | | | | | | |
| **Date of this serious adverse event**  (date started or occurred, whichever is earliest (DD/MM/YYYY)) | | |  | | | | |
| **What are you reporting:** | | 🞎 Serious Adverse Event (SAE) 🞎 Pregnancy | | | | | |
| **Report type** | | 🞎 Initial  🞎 Follow-up\* report number: \_\_\_\_\_\_\_\_  \* For follow-up report only complete sections that have been updated or were incomplete in the initial or previous follow-up report | | | | | |
| **Protocol ID** | |  | | | |  | |
| **Principal Investigator Name** | |  | | | |  | |
| **Site number** | |  | | | |  | |
| **Participant ID** | | \_ \_ / \_ \_ / \_ \_ \_ | | | |  | |
| **Participant DOB** | |  | | | |  | |
| **Randomisation number** | |  | | | | | |
| **Date of randomisation** | |  | | | | | |
| **Study Design** | 🞎 Open-label | | | 🞎 Double-blind | | | 🞎 Single-blind |
| **Study Intervention Details**  \*for blinded, placebo controlled trials, specify ‘name of intervention/placebo’\* | | | | | | | |
| **Intervention 1** | | Name: | | | | | |
| Dose: | | | | | |
| Route: | | | | | |
| Batch #: | | | | | |
| Start date: | | | | | |
|  | | Stop date (if applicable): | | | | | |
| **Intervention 2**  🞎 Not Applicable | | Name: | | | | | |
| Dose: | | | | | |
| Route: | | | | | |
| Batch #: | | | | | |
| Start date: | | | | | |
| Stop date (if applicable): | | | | | |
| **Link to AE log/eCRF** | | | | | | | |
| **AE line number** | |  | **SAE Occurrence Number** | |  | | |
| **Serious Adverse Event (SAE) Details** | | | | | | | |
| **SAE Term**  \*The Event Term recorded on the Adverse Events log and eCRF with the corresponding AE Line # | | | *Needs to be a term listed in the NCI CTCAE*  *NB death is not an SAE, only an outcome.* | | | | |
| **Date of awareness of this SAE** | | |  | | | | |
| **Stage of study when event occurred or started** | | | 🞎 1: Stage -1: Pre-commencement  🞎 2: Stage 0: Baseline  🞎 3: Intervention period  🞎 4: Follow-up  🞎 5: Post-study (incidental finding) | | | | |
| **Main underlying diagnosis resulting in this SAE**  *If Disease progression led to death, then the diagnosis of the underlying disease should be entered. Sepsis caused delirium, heart attack caused death* | | |  | | | | |
| **Narrative/ Summary of the history leading up to this event** | | | | | | | |
| *Any information that can explain the circumstances of the event, in order to enable an external evaluation of the event.* | | | | | | | |
| **Classification based on physiological organ level**  \*Refer to the version of the NCI criteria for adverse events referenced in the protocol | | |  | | | | |
| **Grading of the event (NCI criteria)** | | | 🞎 1: Grade 1  🞎 2: Grade 2  🞎 3: Grade 3  🞎 4: Grade 4  🞎 5: Grade 5  🞎 99: No specific gradable symptom but meets the criteria for SAE (or pregnancy) | | | | |
| **SAE type** | | | 🞎 1: Results in death  🞎 2: Life-threatening  🞎 3: Inpatient hospitalisation  🞎 3: Prolongation of existing hospitalisation  🞎 4: Results in persistent or significant disability/incapacity  🞎 5: Congenital anomaly or birth defect  🞎 6: Other medically relevant condition judged as serious  🞎 7: Other event with NCI grade of 4 or 5  🞎 8: Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| **Relatedness to the study intervention**  **\****(if blinded placebo-controlled study, assume that all participants are on the active medication and refer to the IB or product information for the list of expected symptoms of interest and side effects).* | | | 🞎 1: Unrelated  🞎 2: Unlikely  🞎 3: Possible  🞎 4: Probable  🞎 5: Definite | | | | |
| **Possible causes of the SAE other than study intervention** | | | 🞎 1: Medical condition  🞎 2: Lack of efficacy  🞎 3: Withdrawal of intervention  🞎 4: Concomitant medication (e.g. adverse drug reaction)  🞎 5: Activity related to study participation  🞎 6: Disease under study  🞎 7: None  🞎 8: Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| **Action taken with study intervention** | | | 🞎 1: None  🞎 2: Discontinued  🞎 3: Discontinued temporarily  🞎 4: Dose modification  🞎 5: Dose modified temporarily | | | | |
| **Other action** | | | 🞎 1: Remedial drug therapy  🞎 2: Non-drug treatment  🞎 3: Hospitalisation  🞎 4: Not able to be determined  🞎 5: None  🞎 6: Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| **Was the patient withdrawn from the study as a result of this SAE?** | | | 🞎 Yes  🞎 No | | | | |

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| **Clinical course and outcome**  Summary of the key investigations, diagnostic tests, treatments and patient response (update Concurrent medications log and eCRF if appropriate), similar to a discharge summary. | |
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| **Outcome of the SAE** | 🞎 1: Resolved  🞎 2: Resolved with sequelae  🞎 3: Change in grade  🞎 4: Ongoing at end of the study  🞎 5: Death  🞎 6: Unknown |
| **Date of outcome (DD/MM/YYYY)**  The date of outcome of the event. If the outcome is ‘ongoing at end of study’ or ‘unknown’ this is the date of the last study visit/contact.  If outcome is ‘death’, enter the ‘date of death’ |  |
| **Is this SAE exempt from ITCC reporting as described within the study protocol?**  *(All SAES are to be recorded irrespective of the exemption)* | 🞎 No- 24-hour reporting is required  🞎 Yes- planned admission  🞎 Yes- admission due to underlying disease process  🞎 Yes- Deterioration due to underlying disease  🞎 Yes- Death due to underlying disease  🞎 Yes- Other exemption applies |
| *NOTE: All Serious Adverse Events are to be followed until resolution. The outcome of the SAE must be completed on the adverse event log and eCRF.* | |

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| **CONTACT DETAILS OF REPORTING PERSON** | | | | |
| **Full name** |  | | | |
| **Study role** |  | | | |
| **Contact telephone** |  | **Email** | |  |
| **Signature** |  | | | |
| **Dated** |  | | | |
| **INVESTIGATOR / MEDICALLY QUALIFIED DELEGATE ASSESSING THIS EVENT** | | | | | |
| As the site investigator, I have reviewed the relevant patient notes, made the required notations, checked the assessments and reporting requirements and have checked the accuracy of this report. | | | | | |
| **Full name** | |  | | | |
| **Study role** | |  | | | |
| **Contact telephone** | |  | | **Email** |  |
| **Signature** | |  | | | |
| **Dated** | |  | | | |
| **This form must be sent to the IMPACCT Trials Coordination Centre within 24 hours**  **of any trial site member becoming aware of a Serious Adverse Event**  **Email:** [**itcc@uts.edu.au**](mailto:itcc@uts.edu.au)  **THE ORIGINAL REPORT MUST BE RETAINED IN THE INVESTIGATOR SITE FILE** | | | | | |