When reporting dates use dd/mmm/yy

Protocol ID:

Participant study number:

Submit SAE reports to: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Participant details**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Participant initials: | Male | Female |  Initial report  Follow-up report | Date of this report: |
| Date of birth or age at time of event | Weight at time of event (if known):\_\_\_\_\_\_\_kg  | Date PI notified of event: |

**Investigator details**

|  |
| --- |
| Investigator name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone #:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Study Site Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |

**Investigational product(s)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Name (indicate if unblended or not) | Batch number | Dose & frequency | Route | Start date/time | Stop date/time (or ongoing) | Indication for use | Causality assessment  |
|  |  |  |  |  |  |  |  |
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|  |  |

**\* Causality: 1=Definite, 2=Probable, 3=Possible, 4=Unlikely, 5=Unknown**

**Concomitant medicines/treatments at time of event, i.e. not to treat event (or attach copy of relevant case record form)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Name | Dose & frequency | Route | Start date/time | Stop date/time (or ongoing) | Indication for use | Possibly causal?Yes/No |
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| --- | --- | --- | --- |
| **Event onset date:**  | **Event onset time:**  | **Event resolved date:** | **Event resolved time:** |
| **Event description: (including dates of hospitalisation, diagnosis and de-challenge/re-challenge, where available)**If necessary please continue event description on Supplementary Information Sheet Mark (x) if used |

Protocol ID:

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| --- | --- |
| **Why was the event serious? (mark ALL that apply X)** | **Outcome at the time of this report** |
| Fatal |  | Resolved |  |
| Life-threatening |  | Recovered with long term sequelae |  |
| New/prolonged in-patient hospitalisation |  | Condition worsened |  |
| Persistent or significant disability/incapacity |  | Not available |  |
| Congenital anomaly / birth defect |  | Fatal |  |
| Medically significant otherwise |  | If outcome was fatal, date of death: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Autopsy findings (or attach): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Required intervention to prevent one of the above outcomes |  |

**Treatment of event (or attach copy of concomitant medication CRF)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name of medication/treatment | Dose & frequency | Route | Start date/time | Stop date/time (or ongoing) | Indication for use |
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**Relevant laboratory/diagnostic tests:**

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| --- | --- | --- |
| **Date** | **Test** | **Results (or pending)** |
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| **Relevant Medical History - continue on Supplementary Information Sheet**  |
| **Date** | **Disease/surgery** |
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Protocol ID:

Participant study number:

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| SUPPLEMENTARY INFORMATION |
| Please indicate the section to which supplementary Information refers:  |
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| Reporter (Title and name):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| For Sponsor use:  |
| Date received in house:  |
| Date reviewed: Reviewer’s name/role:  |
| Recommended action:  |
|  |