**JOINT RESEARCH & ENTERPRISE SERVICES**

**SERIOUS ADVERSE EVENT REPORTING FORM**

Email adverseevents@sgul.ac.uk within 24 hours of identification of event

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| --- |
| 1. Study Short Title:
 |
| 1. Sponsor Study ID:
 |
| 1. Chief Investigator:
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| 1. Site Name:
 |
| 1. Study Site PI:
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| --- |
| SAE ID: (Short study title + **Patient Study ID** + *Participant SAE number*, e.g. TEST **020** *01*) |

1. **Initial Report** [ ]  **Update** [ ]  **Number……………..**

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| --- |
| 1. Patient trial/study ID:
 |
| 1. Date PI/site became aware of event:

*dd/mm/yyyy* |
| 1. Reason for reporting (if multiple reasons, select most serious):

[ ]  Resulted in death[ ]  Life threatening [ ]  Required inpatient hospitalisation or prolongation of existing hospitalisation[ ]  Persistent or significant disability/incapacity[ ]  Congenital anomaly/defect[ ]  Other important medical condition |

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| --- |
| 1. Main diagnosis/symptom:
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| 1. Severity:

[ ]  Mild [ ]  Moderate[ ]  Severe[ ]  Potentially Life Threatening | 1. SAE Status:

[ ]  Resolved[ ]  Resolved with sequelae (specify)[ ]  Ongoing[ ]  Worsened[ ]  Fatal |
| 1. Date of Onset:

*dd/mm/yyyy* | 1. Date Resolved:

*dd/mm/yyyy* |

**If hospitalised:**

|  |  |
| --- | --- |
| 1. Admission date:

*dd/mm/yyyy*[ ]  (Tick if prior to event, date not required) | 1. Discharge date:

*dd/mm/yyyy* |

**Provide details of any other event(s) relevant to the SAE**

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| --- | --- | --- | --- | --- |
| 1. Event
 | 1. Severity

*1: Mild2: Moderate3: Severe4: Potentially life threatening* | Date of Onset*dd/mm/yyyy* | 1. Status

*1: Resolved**2: Resolved with sequelae**3: Ongoing**4: Worsened**5: Fatal* | Date Resolved*dd/mm/yyyy* |
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| 1. Describe serious adverse event and relevant medical history

Include manifestation and progression of event, any treatments given in response to the events and any relevant tests carried out (*Continue on a separate sheet if necessary)* |
| 1. Diagnostic Test

*(if applicable)* | 1. Date

*dd/mm/yyyy* | 1. Normal Range
 | 1. Result (+ units)
 |
| a. |  |  |  |
| b.  |  |  |  |
| c.  |  |  |  |
| d.  |  |  |  |

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| --- | --- |
| 1. Is the study blinded?
 | 1. Study arm/cycle:
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**IMP Information**

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| 1. Trial drug

Frequency and dose | Date of 1st administration*dd/mm/yyyy* | Date of most recent administration*dd/mm/yyyy* | 1. Route

1: Oral2: Intravenous3: Subcutaneous4: Intramuscular5: Other (specify) | 1. Causal Relationship to SAE

1: Definitely2: Probably3: Possibly4: Unlikely5: Not related6: Not assessable | 1. Expectedness

1: Expected2: Unexpected**(If selected causality 4, 5 and 6, mark as N/A)** | 1. Action taken

1: None2: Dose reduction3: Treatment delayed4: Treatment reduced and delayed5: Treatment stopped6: Code break ***(for blinded studies only)*** |
| a. |  |  |  |  |  |  |
| b. |  |  |  |  |  |  |
| c.  |  |  |  |  |  |  |
| d. |  |  |  |  |  |  |

**Concomitant Medications**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. Medication
 | Total Daily Dose | 1. Route

1: Oral2: Intravenous3: Subcutaneous4: Intramuscular5: Other (specify) | 1. Indication for prescription
 | 1. Start date

*dd/mm/yyyy* | 1. Ongoing
 | 1. End date

*dd/mm/yyyy* |
| a. |  |  |  |  |  |  |
| b. |  |  |  |  |  |  |
| c. |  |  |  |  |  |  |
| d. |  |  |  |  |  |  |

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| **Name of person completing form:** **Signature:**  | **Date** |
| **Study Site PI Signature:** | **Date** |

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| **Clinical Reviewer use only** Date assessed by clinical reviewer: Name of clinical reviewer: Signature of clinical reviewer:  |
| Event defined as: [ ]  AE (Downgraded Event)[ ]  SAE[ ]  SAR[ ]  SUSAR (non-life threatening – 14 days)[ ]  SUSAR (life threatening – 7 days) |
| Comments:  |

**Guidance in SAE reporting**

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| **Term** | **Definition** |
| **Adverse Event (AE)** | Any untoward medical occurrence in a patient or clinical trial subject to whom a medicinal product has been administered including occurrences which are not necessarily caused by or related to that product. |
| **Adverse Reaction (AR)** | Any untoward and unintended response to an investigational medicinal product related to any dose administered. |
| **Unexpected Adverse Reaction (UAR)** | An adverse reaction, the nature or severity of which is not consistent with the information about the medicinal product in question set out in the summary of product characteristics (or Investigator brochure) for that product. |
| **Serious Adverse Event (SAE) or Serious Adverse Reaction (SAR) or Suspected Unexpected Serious Adverse Reaction (SUSAR)** | Respectively any adverse event, adverse reaction or unexpected adverse reaction that:* results in death
* is life-threatening
* requires hospitalisation or prolongation of existing hospitalisation
* results in persistent or significant disability or incapacity
* consists of a congenital anomaly or birth defect
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| **Relationship** | **Description** | **Event Type** |
| **Unrelated** | There is no evidence of any causal relationship | SAE |
| **Unlikely** | There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the trial medication). There is another reasonable explanation for the event (e.g. the patient’s clinical condition, other concomitant treatment). | SAE |
| **Possible** | There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of the trial medication). However, the influence of other factors may have contributed to the event (e.g. the patient’s clinical condition, other concomitant treatments). | SAR |
| **Probable** | There is evidence to suggest a causal relationship and the influence of other factors is unlikely. | SAR |
| **Definitely** | There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out. | SAR |