**JOINT RESEARCH & ENTERPRISE SERVICES**

**SERIOUS ADVERSE EVENT REPORTING FORM – MEDICAL DEVICES**

Email to [adverseevents@sgul.ac.uk](mailto:adverseevents@sgul.ac.uk) within **24 hours** of notification.

|  |
| --- |
| 1. Study Short Title: |
| 1. Sponsor Study ID: |
| 1. Chief Investigator: |
| 1. Site Name: |
| 1. Study Site PI: |

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| **Clinical Reviewer use only**  SAE ID: |

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 all that apply):   Resulted in death, injury or permanent impairment to a body structure or a body function  Resulted in a life threatening illness or injury  Required inpatient hospitalisation or prolongation of existing hospitalisation  Required a medical or surgical intervention to prevent life threatening illness  Resulted in a permanent impairment of a body structure or a body function  Led to a congenital anomaly/birth defect  Other important medical condition |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. Event | 1. Severity   *1: Mild 2: Moderate 3: Severe 4: 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: |

**Investigational Device Information**

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| --- | --- | --- | --- | --- | --- | --- |
| 1. Investigational device / Control group / Blinded | Date of 1st use of device/study procedure  *dd/mm/yyyy* | Date of most recent use of device/study procedure  *dd/mm/yyyy* | 1. Relationship to medical device   1: Related 2: Probable 3: Possible 4: Unlikely 5: Unrelated 6: Not assessable | 1. Relationship to study procedure   1: Related 2: Probable 3: Possible 4: Unlikely 5: Unrelated 6: Not assessable | 1. Expectedness   1: Expected 2: Unexpected  **(If selected relationship is 4, 5 or 6, mark as N/A)** | 1. Action taken   1: None 2: Device use stopped temporarily  3. Device use stopped permanently  4. Subject withdrawn 5: Code break ***(for blinded studies only)***  6. Other (please specify) |
| a. |  |  |  |  |  |  |
| b. |  |  |  |  |  |  |
| c. |  |  |  |  |  |  |

**Concomitant Medications**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. Medication | Total Daily Dose | 1. Route   1: Oral 2: Intravenous 3: Subcutaneous 4: Intramuscular 5: 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  Device Deficiency  ADE   SADE  USADE  ASADE |
| Comments: |

**Guidance for SAE Reporting**

**Definitions:**

**Adverse Event (AE)**

Any untoward medical occurrence, unintended disease or injury or any untoward clinical signs (including an abnormal laboratory finding) in subjects, users or other persons whether or not related to the investigational medical device. This definition includes events related to the investigational device or the comparator.

**Adverse Device Event (ADE)**

An adverse event related to the use of an investigational medical device. This includes any adverse event resulting from insufficiencies or inadequacies in the instructions for use, the deployment, the implantation, the installation, the operation or any malfunction of the investigational medical device. This includes any event that is a result of a use error or intentional abnormal use of the investigational medical device.

**Serious Adverse Event (SAE)**

Any Adverse Event that:

* Resulted in death, injury or permanent impairment to a body structure or a body function
* Resulted in a life threatening illness or injury
* Required inpatient hospitalisation or prolongation of existing hospitalisation
* Required a medical or surgical intervention to prevent life threatening illness
* Resulted in a permanent impairment of a body structure or a body function
* Led to a congenital anomaly/birth defect
* Other important medical condition

Device deficiencies that might have led to a serious adverse event where a suitable action had not been taken or an intervention had not been made, or if circumstances had been less fortunate, are reported as an SAE.

Important medical events that may jeopardise the subject or may require intervention to prevent one of the outcomes listed above should also be considered as serious, eg: overdoses (accidental or intentional); pregnancy (of subject or their partner); AE and/or laboratory abnormalities which are listed in the trial protocol as critical to safety evaluations and require reporting.

**Serious Adverse Device Effect (SADE)**

Any adverse device effect that results in any of the consequences characteristic of a Serious Adverse Event.

**Device Deficiency**

Inadequacy of an investigational medical device related to its identity, quality, durability, reliability, safety or performance. This may include malfunctions, user error or inadequacy in the information supplied by the manufacturer.

**Unanticipated Serious Adverse Device Effect (USADE)**

A Serious Adverse Device which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.

**Anticipated Serious Adverse Device Effect (ASADE)**

An effect which by its nature, incidence, severity or outcome has been previously identified in the risk analysis report.

**Causality Assessment:**

|  |  |
| --- | --- |
| **Unrelated** | There is no evidence of any causal relationship to the medical device |
| **Unlikely** | The relationship with the use of the investigational medical device seems not relevant and/or the event can be reasonably explained by another cause |
| **Possible** | The relationship with the use of the device is weak but cannot be ruled out completely |
| **Probable** | The relationship with the investigational medical device seems relevant and/or the event cannot be reasonably be explained by another cause |
| **Related** | The event is associated with the investigational medical device beyond reasonable doubt |