**SERIOUS ADVERSE EVENT (SAE) REPORTING FORM – CTIMPs**

The Investigator is responsible for reporting all SAEs, in accordance with the Standard Operating Procedure for the Recording, Management and Reporting of Adverse Events by Investigators (JRO/INV/S05) and as defined by the protocol, to **UCL Joint Research Office (JRO) immediately** (within **24hrs**)of site awareness:

**Email: sae@ucl.ac.uk**

**COMPLETION GUIDELINES:**

* The report fields can be completed electronically (in MS Word) or a blank report can be printed and completed using a black pen.
* All dates should be entered using the **DD-MMM-YYYY** format, i.e. 08-JUN-2018.
* The event must also be documented in the participant’s medical notes and Case Report Form (CRF).
* Ensure **no patient identifiable data** is sent to the JRO, and only send supporting documentation if requested by the JRO.
* The SAE Reporting Form should be filed in the Investigator Site File, along with all relevant correspondence.

**Event Information**

* The event term should be a **diagnosis** as apposed to signs and symptoms, or a procedure. Only list one event per line, and where multiple events are added please ensure they each independently meet a serious criteria.
* The onset date is when the event met a serious criteria and the resolution date is when the event no longer met a serious criteria (e.g. hospital admission and discharge dates). Where symptoms started before a participant was hospitalised, or continued after discharge, additional non-serious adverse events should be added to the CRF as appropriate.

**Investigator Signature**

* The Investigator (or delegated medically qualified person making the causality assessment) **must sign and date** where indicated on the last page. The completed report should be printed, signed and scanned, or an electronic signature added to a pdf file of the report, using Adobe or DocuSign.

**Follow-up Reports**

* Where information is not available at the time of reporting the SAE ensure all sections are completed on a follow-up report:
* If only minor updates are needed, ensure all follow-up information added to the initial report is initialled and dated, or if completing the form electronically use tracked changes in MS Word.
* Ensure the ‘type of report’ box is updated to ‘follow-up’ with the follow-up report number added, and the report is resigned and dated by the Investigator.
* If major updates are needed complete a new SAE Reporting Form
* All follow-up reports must be emailed to the JRO **within 24hrs** of site awareness of the follow-up information.

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| **Study Sponsor Number:** | ***ADD NUMBER*** |
| **Study Name:** | ***ADD SHORT NAME*** |

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| **Reporter Information** | |
| **Reporter Name:** |  |
| **Email:** |  |
| **Phone number:** |  |
| **Job title:** |  |
| **Site:** |  |

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| **Report Details** | | | | | |
| **Type of Report:** | Initial | | | **Date site was first made aware of SAE**: |  |
| Follow-up | If follow-up, add follow-up report #: |  | **Date this report was completed:** |  |
| and SAE ID *(if provided by sponsor)*: |  |

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| **Subject Information** | | | | | | | |
| **Subject Trial ID:** |  | **Gender:** | Male  Female | **Height** (cm): | **Weight** (kg): | **Age at time of SAE onset**: | Years       Months *(if applicable)* |
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| **Serious Adverse Event (SAE) Information** *(if collecting AESIs, update table accordingly)* | | | | | | | | | | | | | | | | |
| **Event Term** | | | | | **Onset Date** | | | **Outcome** | | **Resolution Date** | | **Serious Criteria** | | **Severity** *(adapt as per protocol)* | | **Causality Relationship to IMP** |
| List **one event** per line  Provide final diagnosis, if known  (signs and symptoms / procedures can be documented in Event Description section on final page) | | | | | DD-MMM-YYYY | | | 1. Recovered 2. Recovering 3. Not Recovered 4. Recovered with Sequelae 5. Fatal 6. Unknown | | DD-MMM-YYYY | | 1. Death 2. Life-threatening 3. Required / Prolonged Hospitalisation 4. Persistent or Significant Disability / Incapacity 5. Congenital Anomaly / Birth Defect 6. Important Medical Event | | 1. Grade 1 2. Grade 2 3. Grade 3 4. Grade 4 5. Grade 5   *Or* Mild, Moderate, Severe | | 1. Related (Reasonable Possibility)  2. Not Related (No Reasonable Possibility) |
| 1. |  | | | |  | | |  | |  | |  | |  | |  |
| 2. |  | | | |  | | |  | |  | |  | |  | |  |
| 3. |  | | | |  | | |  | |  | |  | |  | |  |
| **Provide details of the underlying cause of the event if not related to IMP:** | | | | | | | | | | | | | | | | |
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| **Hospitalisation Information:** | | | Admission Date: | | |  | | | Discharge Date: | |  | | | | | |
| **Death Information:** | | Date of Death: | |  | | | Autopsy performed: | | | Y  N  Unknown | | | Cause of Death: | |  | |

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| **Investigational Medicinal Product (IMP) Information** *amend/pre-fill per protocol* | | | | | | | | | | | |
| **IMP(s)**  **subject was receiving** | **Dose** | | **Frequency** | | | **Route** | **Start date** | | **Ongoing** | **End date** | |
|  |  | |  | | |  |  | | Y  N |  | |
|  |  | |  | | |  |  | | Y  N |  | |
|  |  | |  | | |  |  | | Y  N |  | |
| Date of last dose of IMP prior to SAE: | |  | |  | IMP not started (subject in screening) | | | Was study drug unblinded? *Remove for open label trials* | | | Y  N |

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| **Action Taken with IMP in Response to SAE** *amend/pre-fill per protocol* | | | | | | | |
| **IMP** | **Dose Not Changed** | | **Dose Reduced** | **Dose Increased** | **Drug Withdrawn** | **Unknown** | **Not Applicable** |
| *Add IMP (s)* |  | |  |  |  |  |  |
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|  |  | |  |  |  |  |  |
| **Dechallenge / Rechallenge**  *(complete if dose reduced/drug withdrawn)* | | Did event stop after discontinuation?  Yes  No  Unknown | | | Did event reappear after restart?  Yes  No  Unknown | | |

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| **Non-Investigational Medicinal Product(s) (nIMP(s))** *remove this section if no nIMPs specified in trial* | | | | | | |
| **Medication** | **Dose** | **Frequency** | **Route** | **Start date** | **Ongoing** | **End Date** |
|  |  |  |  |  | Y  N |  |
|  |  |  |  |  | Y  N |  |

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| **Concomitant Medication** *(Ensure information reflects CRF)* | | | | | | | |
| **Any concomitant medication in the 30 days prior to event onset?** | | | Yes  No *(if yes, provide details below and continue on a separate sheet if necessary)* | | | | |
| **Medication** | **Dose** | **Frequency** | | **Route** | **Start date** | **Ongoing** | **End date** |
|  |  |  | |  |  | Y  N |  |
|  |  |  | |  |  | Y  N |  |
|  |  |  | |  |  | Y  N |  |

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| **Relevant Medical History** *(Ensure information reflects CRF)* | | | | |
| **Any relevant medical history?** | Yes  No *(if yes, provide details below and continue on a separate sheet if necessary)* | | | |
| **Medical history / Concurrent condition** | | **Start date** | **Ongoing** | **End date** |
|  | |  | Y  N |  |
|  | |  | Y  N |  |
|  | |  | Y  N |  |

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| **Treatment given for SAE** *(Ensure medications are added to the CRF)* | | | | | | | |
| **Any treatment given for SAE?** | Yes  No *(if yes, provide details below and continue on a separate sheet if necessary)* | | | | | | |
| **Medication** | | **Dose** | **Frequency** | **Route** | **Start date** | **Ongoing** | **End date** |
|  | |  |  |  |  | Y  N |  |
|  | |  |  |  |  | Y  N |  |
|  | |  |  |  |  | Y  N |  |

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| **Relevant Laboratory / Diagnostic Tests** | | | |
| **Any relevant laboratory / diagnostic tests performed?** | Yes  No *(if yes, provide details below and continue on a separate sheet if necessary)* | | |
| **Test name** | | **Test date** | **Results** *(with units and reference ranges if known)* |
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| **Event Description**  *Provide a detailed chronological summary of the event from onset to resolution, including any associated non-serious adverse events, treatments provided, procedures performed and laboratory/diagnostic testing relevant to the SAE. Include details of any suspected interactions between IMP and nIMPs - delete if N/A Continue on a separate sheet if necessary.* | | | | | |
|  | | | | | |
| **Name of person making causality assessment:**  *(Delegated medically qualified person)* |  | **Signature:** |  | **Date:** |  |
| **Name of person completing the form:**  *(if different to person above)* |  | | | | |