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

* Send completed, signed SAE Reporting Form to **UCL Joint Research Office within 24hrs of site awareness of the event:**

Email: **sae@ucl.ac.uk** or fax: **020 3108 2312**

* Please complete all sections, and enter dates as DD-MMM-YYYY,*i.e. 08-JUN-2018***.**
* For follow-up reports please initial and date all changes made, or complete a new SAE reporting form with the updated information. Send to the JRO within 24hrs of site awareness of the new information. The Investigator must re-sign and date the follow-up report.
* Redact all patient identifiable data from any supporting documentation sent to the JRO.
* The SAE Reporting Form should be filed in the Trial Master File / Investigator Site File, along with any relevant correspondence.
* Please ensure the event is also documented in the patient’s medical notes, Case Report Form and SAE log.

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| **Study Sponsor Number:**  | **Study 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 #:  |       | **Date this report was completed:** |       |

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| **Subject Information** |
| **Subject Trial ID:**  |       | **Gender:**  | [ ]  Male [ ]  Female | **Height** (cm):  | **Weight** (kg): | **Age at time of SAE onset**: |       Years  |
|       |       |

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| **Serious Adverse Event (SAE) Information** |
| **Event Term** | **Onset Date** | **Outcome** | **Resolution Date** | **Serious Criteria** | **Severity**  | **Causality Relationship to IMP** |
| List one event per lineProvide 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 alternative causality if not related/unlikely related to IMP:** |
|       |
| **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** |
| **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? *If applicable* | [ ]  Y [ ]  N |

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| **Action Taken with IMP in Response to SAE** |
| **IMP** | **Dose Not Changed** | **Dose Reduced** | **Dose Increased** | **Drug Withdrawn** | **Unknown** | **Not Applicable** |
|       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| **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))** *if applicable* |
| **Medication** | **Dose** | **Frequency** | **Route** | **Start date** | **Ongoing** | **End Date** |
|       |       |       |       |       | [ ]  Y [ ]  N |       |
|       |       |       |       |       | [ ]  Y [ ]  N |       |

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| **Concomitant Medication** |
| **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** |
| **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** |
| **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 (if applicable)- 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)* |       |