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| **Serious Adverse Event / Serious Adverse Reaction Reporting Form** | **Joint r&d office**  **Fax No 020 7905 2201** |
| Initial Report……  Follow-up Report |

SAE/R

REPORTING FORM

**Definition of SAE:** An SAE can be defined as*: an untoward medical occurrence in a subject during clinical research involving a pharmaceutical product, medical device, or clinical intervention that: is fatal; is life threatening; results in persistent or significant disability / incapacity; requires inpatient hospitalisation or prolongs a current hospitalisation; results in a congenital anomaly in offspring; or an event that may jeopardise the participant or may require intervention to prevent one of the outcomes listed above.*

**Initial Reporting:** For all initial reporting of any Serious Adverse Events this form must be completed **fully or with as much information as possible** (hard copy or fax) and sent to the Joint R&D Office within 24 hours of the incident occurring or being known.

**Follow-up Information:** For subsequent follow-up reporting of an SAE/R, a new SAE/R reporting form should be completed with just administration details and all new or missing information **only filled in** and forwarded to the Joint R&D Office as soon as possible. All SAE/Rs must be followed up until closure.

**SUSARs/Expedited Reporting:** For any Suspected Unexpected Serious Adverse Reactions (SUSARs) which are life threatening/fatal, initial reports must be sent to the Competent Authority (CA) and the Main Research Ethics Committee (REC) by the Sponsor within 7 days of being aware of the event. Follow-up information must be sent to the CA and Main REC within 8 days after initial reporting. All other SUSARs must be reported within 15 days and any follow up information sent to the CA and Main REC as soon as possible. A copy of these reports must be sent to the Joint R&D office if this duty has been delegated by the Sponsor to the CI/PI.

Please complete details of any SAE from the time of informed consent in connection with SOP05 for investigators. For guidance on which events to report please refer to the study protocol.

**SEVERITY**

**Mild**: awareness of signs or symptoms, but easily tolerated

**Moderate**: uncomfortable enough to cause interference with usual activity

**Severe**: incapacity with inability to work or do usual activity

**Please email this form to the Joint R&D Office on** [**CTIMP.safety@gosh.nhs.uk**](mailto:CTIMP.safety@gosh.nhs.uk) **(If not, fax on 020 7905 2201) within 24 hours of notification of the event.**

Serious Adverse Event / Reaction Reporting Form

Please complete details of any SAE from the time of informed consent. For guidance on which events to report please refer to the study protocol.

**Please fax this form to the Joint Institute of Child Health and Great Ormond Street Hospital for Children NHS Trust R&D Office on 020 7905 2201 within 24 hours of notification of the event.**

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| 1. **Study details** | | | | | |
| **Study title** |  | | | | |
| **CTA/DDX/CTX No** |  | **Joint ICH /GOSH R&D Office Project ID** |  | **EudraCT number** |  |
| **Type of report** | **Initial  Follow-up** | | Has the Chief or Principal Investigator been informed of this event prior to the completion of this form? | Yes No | |

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| 1. **Patient / Treatment details** | | | | | | |
| **Patient initials** |  | | **Patient study number** | |  | |
| **Date of birth** | DD/MM/YYYY | | **Height** | cm | **Weight** | kg |
| **Gender** | Male | Female | **Was study drug unblinded?** | | **Yes No Not Applicable** | |
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| **Trial IMP** | | **Dose (mg)** | **Route of administration** | **Date of dose initiated** | | **Ongoing?** | **End date (if applicable)** |
|  | |  |  | DD/MM/YYYY | | Y N | DD/MM/YYYY |
|  | |  |  | DD/MM/YYYY | | Y N | DD/MM/YYYY |
|  | |  |  | DD/MM/YYYY | | Y N | DD/MM/YYYY |
| **Date of last treatment given prior to SAE** | DD/MM/YYYY | | **Most recent cycle number**  **(if applicable)** |  | **Was treatment given at full dose prior to event?\*** | Y N | **\***Specify: |
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| **Did reaction abate after study medication stopped?** | **Yes No N/A** | **Did reaction reappear after reintroduction of study medication?** | **Yes NoN/A** |

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| 1. **Serious Adverse Event** | | | | | | | | | | | |
| **COMPLETE THIS PAGE FOR EACH SERIOUS ADVERSE EVENT (photocopy as necessary for each event)** | | | | | | | | | | | |
| **Serious Adverse Event** | | | **Severity**  **(Page 1 for definition)** | | **Date Researcher Became Aware of the Event** | | **Date of Onset** | | **Ongoing** | **Date resolved** | |
|  | | | Mild  Moderate  Severe | | DD/MM/YYYY | | DD/MM/YYYY | | Y  N | DD/MM/YYYY | |
| **Why was the event serious?** *(choose most serious)* | | | **Where did the event take place?** | | | | | | | **Outcome** | |
|  | Resulted in death | |  | Home | | | | | |  | Fully recovered |
|  | Life-threatening | |  | Hospital | | Admission date  DD/MM/YYYY | | Discharge date  DD/MM/YYYY | |  | Improving, but not fully recovered |
|  | Required inpatient or prolonged existing hospitalisation | |  | Out-patient clinic | | | | | |  | Recovered with sequelae |
|  | Resulted in persistent or significant disability/incapacity | |  | Nursing Home | | | | | |  | No recovery |
|  | Resulted in congenital anomaly/birth defect | |  | Hospice | | | | | |  | Fatal |
|  | Other Important Medical Event *(specify)* | | Other *(specify*) | | | | | | | Not Assessable | |
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| 1. **Causal relationship of the event to the test IMP *(Is there a reasonable possibility that the event may have been caused by the trial medication?)*** | | | | | | | | | | | | | | | | | | | |
| Trial drug | | | Definitely | | Probably | | Possibly | | | Unlikely | | Not related | | | Not assessable | | Name of person making decision | | |
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|  |  | **Is that event listed in the reference safety document of the trial medication (study protocol, SmPC or Investigator’s Brochure)?** | | | | | | | | | | | | | Yes | | No | | |
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| 1. **Possible causes for the SAE, other than the investigational treatment?** | | | | | | | | | | | | | | | | | | | | | |
| Studied Disease | | | Yes  No | | | | | | | | | | | | | | | | | | |
| Concomitant Disorders | | | Yes  No | | | Specify, | | | | | | | | | | | | | | | |
| Concomitant Medications | | | Yes  No | | | Specify, | | | | | | | | | | | | | | | |
| Procedures related to the Trial Protocol | | | Yes  No | | | Specify, | | | | | | | | | | | | | | | |
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| 1. **Action taken** | | | | | | | | | | | | |
| Trial drug | None | | \*Dose reduction | | | \*Treatment delayed | | \*Treatment delayed and reduced | | Treatment permanently stopped | | Name of person making decision |
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| \**If dose was reduced and/or delayed, please specify length of delay/how much dose was reduced by:* | | | | | | | | | | | | |
| 1. **Treatment given for management of SAE** | | | | | | | | | | | | |
| **Treatment** | | **Dose** | | **Units** | **Route of administration** | | **Start date** | | **Ongoing?** | | **End date** | |
|  | |  | |  |  | | DD/MM/YYYY | | Y  N | | DD/MM/YYYY | |
|  | |  | |  |  | | DD/MM/YYYY | | Y  N | | DD/MM/YYYY | |
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| 1. **Any concomitant medications?** | | **Yes** | | | **No** | | | *(If yes, please specify below and continue on separate sheet if necessary)* | | | | |
| **Treatment** | **Total daily dose** | | **Units** | | **Route of administration** | | | **Start date** | | | **Ongoing?** | **End date** |
|  |  | |  | |  | | | DD/MM/YYYY | | | Y N | DD/MM/YYYY |
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| 1. **Any relevant tests / laboratory data?** | | **Yes** | | | **No** | | | *(If yes, please specify below and continue on separate sheet if necessary or attach print outs)* | | | | |
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| 1. **Any relevant medical history / concurrent conditions?** | | | | | | **Yes** | | | **No** | *(If yes, please specify below and continue on separate sheet if necessary)* | | |
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| 1. **Any other relevant information?** | | **Yes** | | **No** | | | *(If yes, please specify below and continue on separate sheet if necessary)* | | | | | |
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| **12 Event summary description** *(Give a concise medical description of the event including all relevant symptoms.* ***Please specify the grade for all related symptoms and complete page overleaf for all that meet the definition of serious****)* |
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| **Signature**  Authorised health professional |  | **Print name** |  | **Date of report** | DD/MM/YYYY |

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| **For Sponsor / R&D Office use only** | | | | | | | |
| **Date event reported**  DD/MM/YYYY | | | **Date event reviewed**  DD/MM/YYYY | | | **Event No** | |
| **Was the event considered as related to study drug? Related  Not related** | | | | | | | |
| **Assessment of expectedness:(Was the event listed in the study protocol, SmPC or Investigator’s Brochure?)Expected  Unexpected** | | | | | | | |
| **Event considered as** | **SAE SAR  SUSAR** | | | **If event is a SUSAR, Submission deadline (expedited**  **reporting):** | | | DD/MM/YYYY |
| **Date event was recorded on data base** | DD/MM/YYYY | | | **Date report was acknowledged to reporter by Sponsor** | | | DD/MM/YYYY |
| **If event is SAR or SUSAR, date event reported to support departments (Gene Therapy team, Pharmacy) (if relevant)** | | | | DD/MM/YYYY | | | |
| **If SUSAR, date reported to MHRA** | DD/MM/YYYY | | | **If SUSAR, date reported to Main REC/GTAC** | | | DD/MM/YYYY |
| **Reported to all other PIs** | **Yes No N/A** | | | | | | |
| **Comments:** | | | | | | | |
| **Signature** | | **Print name** | | | **Date of review** | | |
|  | |  | | | DD/MM/YYYY | | |
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