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| **Serious Adverse Event (SAE) / Serious Adverse Reaction Reporting Form** | Site Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Site Number\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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**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 electronic) and sent to [**CTIMP.safety@gosh.nhs.uk**](mailto:CTIMP.safety@gosh.nhs.uk) **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 fully, the new information can be written in bold if possible and forward to the Joint R&D Office as soon as possible. All SAE/Rs must be followed up until closure/resolved.

**SUSARs/Expedited Reporting:** All SUSARs must be reported to REC and MHRA within 7 or 15 days by completing SUSAR form online at MHRA website. Please speak to the Clinical Trial team at R&D office for further advice if required.

Please complete details of any SAE from the time of informed consent. For guidance on which events to report as SAE please refer to the study protocol and reference safety information (RSI) which should be IB or SmPC.

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| 1. **Study details** | | | | | |
| **Study title** | |  | | | |
| **Joint ICH /GOSH**  **R&D Office Project ID** | | |  | **EudraCT**  **number** |  |
| **Type of report** | **Initial  Final**  **Follow up  Report No.#** | | | Has the CI/PI 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** | |  | |
| **Age** |  | | **Height** | cm | **Weight** | kg |
| **Gender** | Male | Female | **Was study drug unblinded?** | | **Yes No Not Applicable** | |
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| **Trial IMP** | | **Dose** | **Units** | **Frequ**  **ency** | **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/MYYYY | |  |  | **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  No N/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**  **1=Mild**  **2=Moderate**  **3=Severe** | | | | **Date Researcher Became Aware of the Event** | | **Date of Onset** | | **Ongoing** | **Date resolved** | | |
|  | | |  | | | | DD/MM/YYYY | | DD/MM/YYYY | | Y  N | DD/MM/YYYY | | |
| **Why was the event serious?** *(choose most serious) (Tick whichever applicable)* | | | | | | | **Where did the event take place?***(Tick whichever applicable)* | | | | | **Outcome (Tick as applicable)** | | |
|  | 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 and expectedness of the event to the test IMP *(Is there a reasonable possibility that the event may have been caused by the trial medication?)****(Tick whichever applicable)* | | | | | | | | | | | | | | | | | | | | | | |
| Trial drug | | | Definitely | | Probably | Possibly | | | Unlikely | | | | Not related | | | | Not assessable | | | Name of person making decision | | |
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|  |  | **Expectedness:**  **Is the event listed in the approved RSI i.e. SmPC or IB?**  **RSI version used to assess the expectedness:\_** | | | | | | | | | | | | | | | 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** *(Tick whichever applicable)* | | | | | | | | | | | | |
| 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** | **Frequ**  **ency** | | **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** | **Dose** | **Units** | **Frequency** | **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 & Role** | **Date of report** |
|  |  |  |
| Form completed by if other than health professional |  |  |

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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** | | | | | | | | **Report No.\_\_\_\_** | |
| **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 & Role** | | | | **Date of review** | | |
|  | | |  | | | | DD/MM/YYYY | | |
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