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| **Serious Adverse Event Follow Up Reporting Form**  **Please submit this form to Nottingham University Hospitals NHS Trust Research and Innovation via e-mail to** [**RDSAE@nuh.nhs.uk**](mailto:RDSAE@nuh.nhs.uk) | | | | | | | | |
|  | | | |  | | | | |
| Please select one of the following options:  **CTIMP (Clinical Trial of Investigational Medicinal Product)**  **CIMD (Clinical Investigation of Medical Device)**  **Other** | | | | | | | | |
| **DATE MUST BE ENTERED DD/MMM/YYYY**  **Time must be entered HH:MM** | | | | | | | | |
|  | | | | | | | | |
| **Section 1: Study Information** | | | | | | | | |
| **Study Title:** | MAnnitol for Cerebral oEdema after IntraCerebral Haemorrhage (MACE-ICH) | | | | | | | |
| **Chief Investigator:** | Dr Kailash Krishnan | | | | **Principal Investigator:** | |  | |
| **R&I Ref Number:** | 22SR001 | | | | **EudraCT Number:** | | 2022-000283-22 | |
| **IRAS Number:** | 1004870 | | | | **Site Address/Number:** | |  | |
|  | | | | | | | | |
| **Follow up Report Number:** | |  | **Follow up Report Date:** |  | | **SAE Reference Number:** | |  |
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| **Section 2: Participant Information** | | | | | | | | |

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| **Initials:** |  | **Participant Number:** |  | **Age:** |  | **Sex:** | Male Female |

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| **Section 3: Event Follow Up Information** | | | | | | | | | | | | | | | | | | | | | | |
| **Changes to Event detailed in Initial SAE Report OR new additional event:** | | | | | | Yes (*please add updated event below and complete causality assessment*)  No | | | | | | | | | | | | | | | |  |
| **Updated event** *(if applicable):* | | | | | | 1) | | | | | | | | | | | | | | | | |
| 2) | | | | | | | | | | | | | | | | |
| 3) | | | | | | | | | | | | | | | | |
| **Description of Changes to the Event and Action Taken Since Previous Report:**  *Include dates. Do* ***NOT*** *use abbreviations* | | | | | |  | | | | | | | | | | | | | | | | |
| **Event Outcome** | | | | | | | | | | | | | | | | | | | | | | |
| Fatal *(Give cause of death if known in event description)* | | | | | | | | | | | | | |  | | Date of death | | |  | | | |
| Recovered/Resolved | | | | | | | | | | | | | |  | | Date recovered | | |  | | | |
| Recovered/Resolved with sequelae *(Give detail in event description)* | | | | | | | | | | | | | |  | | Date recovered | | |  | | | |
| On-going *(Give detail in event description)* | | | | | | | | | | | | | |  | |  | | | | | | |
| Unknown at time of report | | | | | | | | | | | | | |  | |
| **Updates to causality assessment if updated event:** | | | | | | | | | | | | | | | | | | | | | | |
| **Event 1** | | | | | | | | | | | | | | | | | | | | | | |
| ***^To be completed by a medically qualified doctor only*** | | | | | | | | | | | | | | | | | | | | | | |
| **^Severity of Event:** |  | | ***^*Causality** | | | |  | | **^Cause of Event:** *(Detail all possible and suspected causes, including relevant medical history)* | | | | | | | | | | | | | |
| Mild |  | | Not related | | | |  | | DETAIL CAUSE OF EVENT | | | | | | | | | | | | | |
| Moderate |  | | Unlikely | | | |  | |
| Severe |  | | Possibly | | | |  | |
|  | | | Probably | | | |  | |
| Definitely | | | |  | |
| **Expectedness Assessment *(if possibly, probably, or definitely related):***  Expected  Unexpected | | | | | | | | | | | | | | | | | | | | | | |
| **Event 2** | | | | | | | | | | | | | | | | | | | | | | |
| ***^To be completed by a medically qualified doctor only*** | | | | | | | | | | | | | | | | | | | | | | |
| **^Severity of Event:** |  | | ***^*Causality** | | | |  | | **^Cause of Event:** *(Detail all possible and suspected causes, including relevant medical history)* | | | | | | | | | | | | | |
| Mild |  | | Not related | | | |  | | DETAIL CAUSE OF EVENT | | | | | | | | | | | | | |
| Moderate |  | | Unlikely | | | |  | |
| Severe |  | | Possibly | | | |  | |
|  | | | Probably | | | |  | |
| Definitely | | | |  | |
| **Expectedness Assessment *(if possibly, probably, or definitely related):***  Expected  Unexpected | | | | | | | | | | | | | | | | | | | | | | |
| **Event 3** | | | | | | | | | | | | | | | | | | | | | | |
| ***^To be completed by a medically qualified doctor only*** | | | | | | | | | | | | | | | | | | | | | | |
| **^Severity of Event:** |  | | ***^*Causality** | | | |  | | **^Cause of Event:** *(Detail all possible and suspected causes, including relevant medical history)* | | | | | | | | | | | | | |
| Mild |  | | Not related | | | |  | | DETAIL CAUSE OF EVENT | | | | | | | | | | | | | |
| Moderate |  | | Unlikely | | | |  | |
| Severe |  | | Possibly | | | |  | |
|  | | | Probably | | | |  | |
| Definitely | | | |  | |
| **Expectedness Assessment *(if possibly, probably, or definitely related):***  Expected  Unexpected | | | | | | | | | | | | | | | | | | | | | | |
| **^Section Completed by:** | | | NAME | | | | | | | | | SIGNATURE | | | | | | | | DATE | | |
| *Name (PRINT)* | | | | | | | | | *Signature* | | | | | | | | *Date* | | |
|  | | | | | | | | | | | | | | | | | | | | | | |
| **Section 4: Concomitant Medication Information** | | | | | | | | | | | | | | | | | | | | | | |
| **Participant has received Concomitant Medication** | | | | No | | | | | | | | | | | | | | | | | | |
| Yes *(Provide details below)* | | | | | | | | | | | | | | | | | | |
| **Name of Medication** | | | | **Indication(s) for Use** | | | | | | **Dose (units)** | | | **Route of Administration** | | | | **Date of First Administration** | | | | **Date of Last Administration** | |
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| **Continuation sheet attached** *(Tick if additional* ***concomitant medication*** *is listed on a separate sheet and indicate number of pages)* | | | | | | | | | | | | | | | | | | | | | | |
| **Section 5: Participant Status** | | | | | | | | | | | | | | | | | | | | | | |
| **Blind Broken:** | | | | | Not Applicable | | | | | | Yes | | | | | No | | | | | | |
| Continuing in the trial | | | | | | | |  | | | | | | | | | | | | | | |
| Completed the trial | | | | | | | | **Date of Completion:** | | | | | | |  | | | | | | | |
| Withdrawn from the trial | | | | | | | | **Date of Withdrawal:** | | | | | | |  | | | | | | | |
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| **Section 6: Additional Information** | | | | | | | | | | | | | | | | | | | | | | |
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| **Section 7: Completion Details** | | | | | | | | | | | | | | | | | | | | | | |
| **Report Completed by:** | |  | | | |  | | | | | | | | | | | |  | | | | |
| *Name (PRINT)* | | | | *Signature* | | | | | | | | | | | | *Date* | | | | |
| **PI Review:**  *(If not reporter)* | |  | | | |  | | | | | | | | | | | |  | | | | |
| *Name (PRINT)* | | | | *Signature* | | | | | | | | | | | | *Date* | | | | |

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| **FOR SPONSOR USE ONLY** | | | | | | | |
| **Initial Report Date:** |  | |  | | | | |
| **Report Received by:** |  | |  | | |  | |
| *Name (PRINT)* | | *Date* | | | *Time* | |
| **Report Checked and Tracked by:** |  | |  | | |  | |
| *Name (PRINT)* | | *Date* | | | *Time* | |
| **Comments:** |  | | | | | | |
|  |  | | |  |  | |  |
| **Assessment by R&I Clinical Research Physician:** | | | | | | | |
| **Reference Safety Information Used for Expectedness Assessment (please also detail version):** | |  | | | | | |
| **Initial MedDRA Code:** | |  | | | | | |
| **MedDRA Code change required?** | | Yes (*please add event information below and complete causality assessment*)  No | | | | | |

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| **Event 1) MedDRA Code:** | | | | |
| **Event term** | **SOC** | **SOC code** | **LLT** | **LLT code** |
|  |  |  |  |  |
| **Causality Assessment:** | Not Related (SAE) | **Expectedness Assessment:**  *(if related)* | Expected (SAR) | |
| Related (SAR) | Unexpected **(SUSAR)** | |
| **Event 2) MedDRA Code:** | | | | |
| **Event term** | **SOC** | **SOC code** | **LLT** | **LLT code** |
|  |  |  |  |  |
| **Causality Assessment:** | Not Related (SAE) | **Expectedness Assessment:**  *(if related)* | Expected (SAR) | |
| Related (SAR) | Unexpected **(SUSAR)** | |
| **Event 3) MedDRA Code:** | | | | |
| **Event term** | **SOC** | **SOC code** | **LLT** | **LLT code** |
|  |  |  |  |  |
| **Causality Assessment:** | Not Related (SAE) | **Expectedness Assessment:**  *(if related)* | Expected (SAR) | |
| Related (SAR) | Unexpected **(SUSAR)** | |
| *If additional MedDRA terms and causality assessments are required, please provide this as an appendix.* | | | | |
| **Further follow up required:**  Yes  No | | | | |

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| --- | --- | --- | --- |
| **Comments:** |  | | |
| **Assessment Completed by:** |  |  |  |
| *Name (PRINT)* | *Signature* | *Date* |