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| R &I New image.PNG | | | | | | | | | | | | | | | | | | | | | | | | |
| **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) | | | | | | | | | | | | | | | | | | | | | | | | |
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| 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** | | | | | | | | | | | | | | | | | | | | | | | | |
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| **Section 1: Study Information** | | | | | | | | | | | | | | | | | | | | | | | | |
| **Study Title:** | | MAnnitol for Cerebral oEdema after IntraCerebral Haemorrhage (MACE-ICH): a feasibility trial | | | | | | | | | | | | | | | | | | | | | | |
| **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:** | | | |  | | |
|  | |  | | | | | | | | | | | |  | | | | | |  | | | | |
| **Section 2: Participant Information** | | | | | | | | | | | | | | | | | | | | | | | | |
| **Initials:** |  | | | | | | | | | **Participant Number:** | | | | | |  | | | | | | | | |
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| **Section 3: Event Follow Up Information** | | | | | | | | | | | | | | | | | | | | | | | | |
| **No Changes to Event detailed in Initial SAE Report** | | | | | | | |  | | | | **Changes to Event detailed in Initial SAE Report** | | | | | | | | | | | |  |
| **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 | | | | | | | | | | | | | |  | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | |
| **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:** | | | | | | | |  | | | | | | | | | |
|  | | | | | | |  | | | | | | | |  | | | | | | | | | |
| **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:** | | | | | | | | | | |
| **Initial MedDRA Code:** | |  | **MedDRA Code changed to:**  **(if required):** | | | | | |  | |
| **Comments:** | |  | | | | | | | | |
| **Assessment Completed by:** | |  | | |  | |  | | | |
| *Name (PRINT)* | | | *Signature* | | *Date* | | | |