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| **Effects of Advanced Trauma Life Support ® Training Compared to Standard Care on Adult Trauma Patient Outcomes (ADVANCE TRAUMA): A Cluster Randomised Trial** | |
| *Batch & Site no.:* | |
| *Site name/ hospital:* | |
| *Name of Site Investigator:* | |
| *Date of monitoring:* | |
| *Monitoring number:* | |
| **Site Staff Present** | |
| Name | Position |
|  |  |
|  |  |
| **Project Team/ Sponsor/ Other Representatives Present** | |
| Name | Role |
|  |  |
| **Type of monitoring (select all that apply):**  On-site Monitoring  Site Training    Other (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

Site status at time of monitoring:

Activated, no participants recruited  Recruitment ongoing

Recruitment completed; Follow-up ongoing  Participants recruitment and follow-up completed

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| **Participants** | **Number** |
| Planned |  |
| Screened |  |
| Ineligible |  |
| Completed |  |
| Ongoing |  |
| Total Withdrawn |  |
| Lost to Follow Up |  |

*On the table below, please tick the appropriate box for each item. Also insert comments, providing specific information, issues, and actions for follow-up. Please number any actions/follow-up and match the item number (1, 2 etc.) in the Actions and Follow-up table below.*

| **Item** |  |  |  |
| --- | --- | --- | --- |
| **Screening & Enrolment** | **Yes** | **No** | **Comments/ observations or follow up item #** |
| Have the screening and eligibility has been properly done? |  |  | *Ensure the site has correctly identified participants* |
| Are the required number of participants being recruited is as per the set timelines? |  |  | *List reasons for premature withdrawals. Refer to screening and enrolment logs.* |
| Did all the participants enrolled is as per the resident’s duty roster |  |  | *Check the duty roster shared by the sites and the days of data collection* |
| **Informed Consent** | **Yes** | **No** | **Comment or follow up item #** |
| Were all participants consented correctly? |  |  | *Participants must be consented according to GCP guidelines. List all errors and highlight any Protocol Violations.* |
| Is the current IEC approved informed consent document being used? |  |  | *Ensure consent form version and date of consent matches the current approved version and note any incorrect version used.* |
| Are there any enrolled participants who were not consent? |  |  | *Ensure all the participants are consented as per the ICH-GCP and Indian applicable guidelines.* |
| Is the ICF stored in a locked cabinet? |  |  | *Ensure the ICF are stored securely in a locked cabinet* |
| **Randomization** | **Yes** | **No** | **Comment or follow up item #** |
| Adherence to randomisation schedule |  |  | *Ensure the hospital adhere to the randomized schedule* |
| Report the non-adherence reason |  |  | *Report the cause of non-adherence* |
| **Data Collection** | **Yes** | **No** | **Comment or follow up item #** |
| Is the Data collection is done as per the residents’ duty roster |  |  | *Ensure the site is doing data collection on specified days as per the resident’s roster.* |
| Report if any data collected besides the residents’ duty roster |  |  | *Report if any of the data collection was done besides resident’s roster.* |
| **CRF Review** | **Yes** | **No** | **Comment or follow up item #** |
| Were CRFs available for review? |  |  | *Are the CRFs or source data available for review?* |
| Which CRFs were reviewed at this visit? |  |  | *List the items reviewed.* |
| Is CRF reviewed for correctness, completeness. |  |  | *Check the data filled in the CRF is appropriately entered.* |
| Pending CRF data queries reviewed at site? |  |  | *Note remote monitoring/data queries which were pending.* |
| Are CRFs securely stored? |  |  | *Check the location of the CRFs. Remove if tablet* |

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| **Source Documents and Source Data Verification (SDV)** | **Yes** | **No** | **Comment or follow up item #** |
| Were all required source documents available for all screened and enrolled participants? |  |  | *Were the medical records or other source document available for review? Note what was missing.* |
| Has SDV been performed according to Monitoring Plan? |  |  | *Perform SDV as per Monitoring Plan and note any discrepancies.* |
| **Safety** | **Yes** | **No** | **Comment or follow up item #** |
| Have all new safety reports have been properly reviewed, reported, and documented? |  |  | *Review that all safety reports are accurately reported and check for any safety reports not reported.* |
| Have all safety reports been reported to project team/Sponsor/ TMG and IEC within required timelines? |  |  | *If safety reports reporting deadlines to the IEC were not met, a protocol violation has occurred and must be reported.* |
| Is follow-up of all safety reports being addressed, including processing/ reporting of any new information? |  |  | *Check all* safety *reports have been followed up to resolution.* |
| **Protocol Deviations & Violations** | **Yes** | **No** | **Comment or follow up item #** |
| Were there any protocol deviations or violations? |  |  | *Record protocol deviations or violations identified at this visit as per*  *the protocol and monitoring plan* |
| Are protocol deviations are well identified and documented? |  |  | *Ensure the PD/PV log is updated* |
| Were all required source documents available for protocol deviations and violations? |  |  |  |
| Were protocol violations reported to the TMG or IEC as required? |  |  | *According to the IEC condition of reporting and timelines.* |
| Were all the protocol violations reported on time? |  |  |  |
| Are there any protocol violations identified which were not reported? |  |  |  |
| **Investigator Site File (ISF) Review** | **Yes** | **No** | **Comment or follow up item #** |
| Is the ISF complete and up to date? |  |  | *Include details of any missing items.* |
| Have all reports been submitted to IEC as required (including annual progress report) and is IEC acknowledgement/approval on file? |  |  | *Include details of any missing reports, acknowledgments, or approval documents.* |
| Have all required essential documents been submitted to project team/Sponsor? |  |  | *Check versions and missing documents and list for follow-up.* |
| **Process Monitoring** | **Yes** | **No** | **Comment or follow up item #** |
| 1. Screening procedure |  |  | *Ensure to monitor the process listed under process monitoring, write in detail if any of the process needs improvement and what must be improved* |
| 1. Consenting procedure |  |  |  |
| 1. Enrolment procedure |  |  |  |
| 1. eCRF entry |  |  |  |
| 1. Follow-up procedure |  |  |  |
| 1. Review of collection of study procedures like Quality of Life, Disability (WHODAS 2.0), Return to Work, End of Study, Adherence form (if applicable) |  |  |  |
| **Investigator and Site Staff Contact** | **Yes** | **No** | **Comment or follow up item #** |
| Have all significant issues and findings been discussed with the Principal Investigator? (Specify in comments.) |  |  | *Ensure any concerns about PI oversight are documented and, if required, escalated according to* PO-SOP-13*.* |
| Were new or unresolved issues discussed?   1. Recruitment, retention 2. Data queries 3. AE follow-up 4. Other |  |  | *Note what was discussed and any follow-up actions required.* |
| Were meetings conducted with other site staff? |  |  | *List staff present at the discussion.* |
| Are staff and facilities still adequate? |  |  | *List new staff and training needs. Comment on staff resourcing and instrument calibration certificate for the project.* |
| **Other** | **Yes** | **No** | **Comment or follow up item #** |
| Specify: *(e.g., if IEC requires requirements/ other areas identified during the monitoring visit.* |  |  | *List here any other category and items not mentioned above.* |

Documents collected during this visit:  none

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Documents filed in ISF during this monitoring:  none

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Attachments to this report: none

*List out all the enlisted observation*

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| **Item #** | **Description** | **Action Required** | **Due by / responsible** |
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**Actions and follow-up** *Add follow-up items to the Monitoring issues and actions log (PO-AD-04c)*

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| **Item #** | **Issue and action required** | **Person responsible** | **Status and outcome** |
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**Overall Comments**

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| --- | --- |
|  | *Thank you to Cee for your time at this Monitoring Visit and thank you to the team at XXX Hospital for your work on the XXX study name.* |
|  | *Overall, the site has managed the trial very well. The error rate for this visit is very low and data entry at this site is excellent and up to date, thank you.* |

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| **Report prepared by (name):** |  |
| **Signature:** | *Please do not sign until the report has been finalised.* |
| **Role:** |  |
| **Date:** | *The initial draft was submitted by whom on which date; the second draft was submitted by whom on which date; etc.* |
| **Report reviewed by (name):** |  |
| **Signature:** | *Please do not sign until the report has been finalised.* |
| **Role:** |  |
| **Date:** | *The initial review was done by whom on which date; the second review was done by whom on which date; etc.* |

*Please add explanation if the timelines for review according to Monitoring Plan have not been met.*

Reviewer comments, if required:

Original signed document: File in Trial Master File.