Close Out Visit Report

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| Study Details | | | | |
| Study name |  | | | |
| Type of study |  | | | |
| REC reference |  | Lothian R&D reference | |  |
| Edition of COV report (if bespoke) |  | Date |  | |
| Study Site |  | | | |
| PI name |  | | | |
| PI contact details |  | | | |

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| Visit Details | | | | | | | |
| Date of visit |  | | | | Date of last visit |  | |
| Type of visit (✓) | Onsite |  | Remote |  | If remote document justification: | | |
| ACCORD personnel (or designees) present |  | | | | | | |
| Study personnel present |  | | | | | | |
| COV as scheduled by Protocol | Yes ☐ | | No ☐ | | PI seen | Yes ☐ | No ☐ |
| Comments: | | | | | | |
| Visit to supporting departments conducted |  | | | | | | |

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| Site Close Out Checklist | | | | |
| (✓) | | Yes | No | N/A |
| Site close out checklist (CM003-T03) complete | |  |  |  |
| Actions identified on review of site level close out checklist?  *(If yes please list actions in comments box below or relevant section of report).* | |  |  |  |
| Comments: |  | | | |

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| --- | --- | --- | --- | --- |
| Final Participant Recruitment Figures | | | | |
| (✓) | | Yes | No | N/A |
| Recruitment figures documented in site close out checklist reconciled with eCRF/database? | |  |  |  |
| Site level recruitment logs complete? | |  |  |  |
| Comments: |  | | | |

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| Study Files | | | | |
| (✓) | | Yes | No | N/A |
| Does the PI wish to arrange archiving for ISF through site R&D? | |  |  |  |
| Comments: |  | | | |
| (✓) | | Yes | No | N/A |
| If not archiving through site R&D, appropriate plans for archiving trial data in place | |  |  |  |
| ACCORD QA informed of proposed non-R&D archive location? | |  |  |  |
| Comments: |  | | | |
| (✓) | | Yes | No | N/A |
| Individual who will serve as the named contact for archived trial documentation throughout the archiving period has been identified and archiving location recorded in the Site close out checklist? | |  |  |  |
| Comments: |  | | | |
| (✓) | | Yes | No | N/A |
| Archiving period confirmed with PI – documents that may fade over time and thus required to be copied (e.g. ECG traces) identified and discussed | |  |  |  |
| Comments: |  | | | |
| (✓) | | Yes | No | N/A |
| Communicated that all plastic pockets, paperclips, etc should be removed and any identifiable data should be prepared according to local policy before archiving (e.g. sealed in an envelope marked as identifiable data) | |  |  |  |
| Comments: |  | | | |
| (✓) | | Yes | No | N/A |
| Discussed with PI that patient health records will be retained by health records department for the applicable duration e.g. are identified as clinical trial records (by a sticker or electronic alert) and so will not be destroyed during archiving period. | |  |  |  |
| Comments: |  | | | |

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| --- | --- | --- | --- | --- |
|  | Comments | Complete and ready for archive | | |
| (✓) | Yes | No | N/A |
| Investigator Site File | |  |  |  |
| List any documents required to complete ISF and outline plan to recover lost documents: |  | | | |
| List any documents required from site to complete site specific section of TMF |  | | | |

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| Site Closure | | |
| Reason for Site closure *(tick one)* | | ✓ |
| Trial end at site as defined in protocol | |  |
| Trial closed early due to safety concerns | |  |
| Site closed early due to lack of resource | |  |
| Site closed early due to lack of recruitment | |  |
| Other *(specify below)* | |  |
| Comments: |  | |

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| Trial Data | | | | | |
| (✓) | | | Yes | No | N/A |
| Has all trial data been collected at site and is it complete? | | |  |  |  |
| Comments: | | |  | | |
| (✓) | | | Yes | No | N/A |
| Have all data queries been resolved? | | |  |  |  |
| Comments: | | |  | | |
| (✓) | | | Yes | No | N/A |
| Has access to randomisation procedures been removed at site? | | |  |  |  |
| Comments: | | |  | | |
| (✓) | | | Yes | No | N/A |
| Has access to the eCRF/database been removed for staff at site? | | |  |  |  |
| Comments: | | |  | | |
| (✓) | | | Yes | No | N/A |
| Has any centrally collected/eCRF source data been provided to site for archive? | | |  |  |  |
| Detail any specific requirements/arrangements for site level storage of electronic data. Data should be recoverable for duration of archive period. Escalate any new risks identified to QA. | |  | | | |
| Comments: |  | | | | |

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| Monitoring Findings | | | | |
| (✓) | | Yes | No | N/A |
| Have all outstanding monitoring visit actions been resolved?  *N/A if no monitoring visits performed at site* | |  |  |  |
| Comments: |  | | | |

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| Delegation and Training | | | |
| (✓) | | Yes | No |
| Final delegation log reconciled with training log and CVs/GCPs provided for TMF? | |  |  |
| Comments: |  | | |

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| Regulatory Compliance | | | |
| When closing any site (✓) | | Yes | No |
| PI advised that audits and inspections can occur for the trial after site close out | |  |  |
| Site close out checklist confirms that local R&D department has been informed of site closure | |  |  |
| Comments: |  | | |

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| Safety | | | | |
| (✓) | | Yes | No | N/A |
| Reconciliation of SAEs listed in site close out checklist against sponsor’s PV database complete | |  |  |  |
| All SAEs followed up to resolution or as per protocol in PV database | |  |  |  |
| Comments: |  | | | |
| (✓) | | Yes | No | N/A |
| Reconciliation of deviations listed in site close out checklist against records of deviations held by sponsor’s QA office complete | |  |  |  |
| Reconciliation of violations listed in site close out checklist against records of violations held by sponsor’s QA office complete | |  |  |  |
| Comments: |  | | | |

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| IMP/Device/Agent Accountability | | | | | |
| IMP/device/agent used in study Yes ☐ *(complete below)* No ☐ *(skip to next section)* | | | | | |
| (✓) | | Yes | No | Click here to enter a date. | |
| Visit to pharmacy performed? | |  |  |
| (✓) | | | Yes | No | N/A |
| Pharmacy file ready for archive | | |  |  |  |
| Pharmacy file archiving location confirmed in site close out checklist | | |  |  |  |
| Comments |  | | | | |
| (✓) | | | Yes | No | N/A |
| Emergency unblinding tools ready for archive | | |  |  |  |
| If unblinding has occurred, documented as per the protocol | | |  |  |  |
| Site level IMP/agent/device accountability complete | | |  |  |  |
| Temperature logs complete for period IMP/agent/device stored in and/or out with pharmacy. | | |  |  |  |
| Remaining IMP/agent/device destroyed or returned to manufacturer as required | | |  |  |  |
| Comments: |  | | | | |

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| Labs | | | | | |
| Labs involvement in study? - Yes ☐ *(complete below)* No ☐ *(skip to next section)* | | | | | |
| (✓) | | Yes | No | Click here to enter a date. | |
| Visit to labs performed? | |  |  |
| (✓) | | | Yes | No | N/A |
| Site specific lab reference ranges for the duration of the trial will be available for the entire archiving period | | |  |  |  |
| Sample accountability complete | | |  |  |  |
| Comments: |  | | | | |

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| Other Supporting Departments | | | | | |
| Support department involvement in study? - Yes ☐ *(complete below)* No ☐ *(skip to next section)* | | | | | |
| (✓) | | | | Yes | No |
| All supporting departments have been closed out | | | |  |  |
| Supporting Department | Visit performed? (✓) | | | Closed? (✓) | |
| Yes | No | Date | Yes | No |
|  |  |  | Click here to enter a date. |  |  |
|  |  |  | Click here to enter a date. |  |  |
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| Comments: |  | | | | |

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| Comments and Actions | | |
| If COV cannot be completed, document details of all outstanding items below | | |
|  | | |
| Actions for study team | | |
|  | | |
| Actions for ACCORD monitoring team | | |
|  | | |
| (✓) | Yes | No |
| Follow up visit required? |  |  |
| If yes, give details of follow up visit: | | |
|  | | |

NOTE: Transfer actions to monitoring visit action log (CM003-T05) and follow up actions until resolution

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| COV Report Signatures | | | |
| **Report Completion** | | | |
| Author of Report: |  | Role: |  |
| Report Completion Date: | Click here to enter a date. | Date sent for Review: | Click here to enter a date. |
| Signature: |  | Date: |  |
| **Report Review** (if required by monitoring plan) | | | |
| Reviewer of Report: |  | Role: |  |
| Date Report Received: | Click here to enter a date. | Date Review Completed: | Click here to enter a date. |
| Signature: |  | Date: |  |