Study Level Close Out Checklist

|  |  |
| --- | --- |
| Study Title |  |
| Lothian R&D Ref |  | Chief Investigator |  |
| Location of Trial Master File (TMF) |  | Trial Manager |  |

*This is a template – please make study specific as appropriate. To be completed by the Lead Monitor. Please ensure site level close out checklists are completed as appropriate prior to signing this. Actions highlighted in red below must be completed prior to database lock.*

|  |
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| Total Study Recruitment Figures |
| Screened |  |
| Consented |  |
| Screen fails |  |
| Randomised |  |
| Completed |  |
| Withdrawn |  |

|  |  |  |
| --- | --- | --- |
|  | **Date Completed**  | **Comments/Actions** |
| **Essential Documentation** |
| Final TMF review performed with essential document checklist completed (please file alongside this checklist) |  |  |
| All TMF review actions followed up, essential documents filed and TMF ready for archiving |  |  |
| Confirm where TMF will be archived and who is named contact during archiving period – please state address and contact details |  | Address:Name:Tel:Email: |
| Final SF review performed with essential document checklist completed (please file alongside this checklist) |  |  |
| All SF review actions followed up, essential documents filed and SF ready for archiving |  |  |
| CI is aware that all study documentation must be retained as per protocol and cannot be destroyed without permission from the Sponsor |  |  |
| **Pharmacovigilance** |
| SAEs across all sites reconciled with ACCORD PV records and study eCRF/database |  |  |
| ACCORD PV Team have confirmed that all PV documentation is filed as appropriate in TMF/SF |  |  |
| **Deviations and Violations** |
| Deviations across all sites reconciled with ACCORD records* Sponsor listing provided to Statistician
 |  |  |
| Violations across all sites reconciled with ACCORD records* Sponsor listing provided to Statistician
 |  |  |
| **Monitoring** |
| SDV Plan targets met |  |  |
| All monitoring actions complete (e.g. Central or Remote Visit action logs) |  |  |
| **Laboratory** |
| Central lab sample analysis complete |  |  |
| Central lab final sample accountability complete |  |  |
| **Data** |
| Statistical Analysis Plan finalised  |  |  |
| Data QC checks complete |  |  |
| All data queries resolved |  |  |
| All site level close out visits performed |  |  |
| Database fully locked |  |  |
| All site level close out actions resolved |  |  |
| **Results Reporting** |
| End of Trial notification Form submitted as appropriate and within required timeframe – refer to SOP CR009 |  | Date of end of trial reported on notification:  |
| Study Team aware to submit Clinical Study Report/Publication as appropriate – and file note in place to confirm this will be filed in TMF when available (and prior to archiving) if required. Refer to SOP CR011 |  |  |
| Study Team aware to contact QA with end of trial reporting requirements within 12 months of end of trial date. |  |  |

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| **Monitoring Declaration – Adherence to Monitoring and SDV Plans**  |
| I confirm that the monitoring plan for this study has been followed and that all aspects of the SDV plan have been met. Where deviations from the monitoring plan have occurred or where aspects of the SDV plan have not been met the Senior Clinical Trials Monitor, or designee, has been informed. |
| Comments: |
| **NAME** |  | **ROLE** |  |
| **SIGNATURE** |  | **DATE** |  |

|  |
| --- |
| **Checklist Completion** |
| Checklist completed by: |  | Role: |  |
| Signature: |  | Date: | Click here to enter a date. |
| **Checklist Review**  |
| Checklist reviewed by: |  | Role: |  |
| Date Received: | Click here to enter a date. | Date Review Completed: | Click here to enter a date. |
| Signature: |  | Date: | Click here to enter a date. |

**Once fully signed please provide a copy to ACCORD QA team (****qa@accord.scot****)**