

Site Closure Checklist

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| --- | --- |
| **Study Details** | |
| **Study Title:** |  |
| **Principle Investigator Name:** |  |
| **Department:** |  |
| **Site:** |  |
| **Sponsor:** |  |
| **EUDRACT Number:** |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Planned closure |  | Early closure | Reason: |  |

|  |  |  |
| --- | --- | --- |
| **Site Status** | | |
| Confirm site recruitment status at end of trial. *Please add or remove rows as required.* | | |
|  | **N** | **Comments** |
| Participants screened: |  |  |
| Participants ineligible: |  |  |
| Participants randomised: |  |  |
| Received treatment: |  |  |
| Treatment terminated due to AEs: |  |  |
| Treatment terminated due to Other: |  |  |
| Completed treatment: |  |  |
| Lost to follow-up: |  |  |
| Completed follow-up: |  |  |
| SAEs: |  |  |
| Withdrawn: |  |  |
| SUSARs: |  |  |

| ***No.*** | ***Task*** | ***Date Completed*** | ***Comments*** | |
| --- | --- | --- | --- | --- |
| **Case Report Forms (CRFs)/Source Documents** | | | | |
| 1 | Confirm that appropriate source documentation is available for all subjects |  |  | |
| 2 | Paper Studies: Confirm that all CRFs have been completed, collected, and the proper legible copies are present in study files  Electronic Data Capture (EDC) Studies: Confirm that all electronic CRFs have been completed |  |  | |
| 3 | Paper Studies: Confirm that all data queries issued to date have been appropriately resolved, signed and dated by the investigator, and that signed and dated queries are filed with the corresponding CRF page or subject |  |  | |
| **Data Management** | | | | |
| 5 | Confirm all data has been entered into the database |  |  | |
| 6 | Ensure all queries have been issued, returned, and resolved |  |  | |
| 7 | Once all queries have been resolved, clean and QC the database (DM task) |  |  | |
| 8 | Perform database lock (DM task) |  |  | |
| **Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting/Reconciliation** | | | | |
| 9 | Ensure that all AEs, CAPAs, SAEs and SUSARs have been captured, followed and resolved per protocol, and reported to the appropriate parties according to protocol reporting requirements |  |  | |
| 10 | Confirm that all required follow-up documentation has been retrieved, communicated to appropriate parties, and is present in the study files |  |  | |
| **Investigator Site Files** | | | | |
| 11 | Confirm that signed consent forms are on file for all subjects |  | |  |
| 12 | Reconcile study files with Trial Master File (TMF) list. For studies where the TMF is maintained at the lead site, ensure all required documents are present, including collection of all required documents from all Investigator Site Files, where appropriate.  These can include, but are not limited to:   * protocols and amendments * approved consent document templates * IRB approvals * study team licenses * study certification documentation and CVs * laboratory documentation * Standard Operating Procedures (SOPs) |  | |  |
| 13 | Ensure reporting of study closure to the sponsor (and MHRA if CTIMP) and receipt/filing of study closure confirmation in the investigator site files |  | |  |
| 14 | If study was terminated early, confirm notification of study termination has been sent to all enrolled subjects as appropriate |  | |  |
| 15 | Confirm that all protocol deviations and CAPAs have been noted in source documentation and reported as appropriate |  | |  |
| 16 | Consider appropriate storage of Quality Management (QM) reports / metrics |  | |  |
| 17 | Confirm sponsor requirements for record retention and notify NIDCR/sponsor when study files will be transferred to long term off-site storage |  | |  |
| ***Ensure the completeness of the following logs:*** | | | | |
| 18 | Pre-Screening Log (*if applicable)* |  | |  |
| 19 | Subject Screening and Enrollment Log |  | |  |
| 20 | Monitoring Visit Log *(if applicable)* |  | |  |
| 21 | Delegation Log (including end dates) |  | |  |
| 22 | Telephone Log *(if applicable)* |  | |  |
| 23 | Training Log |  | |  |
| 24 | Subject Code List |  | |  |
| 25 | Randomisation Log *(if applicable)* |  | |  |
| 26 | IMP Accountability Log: Stock Record *(if applicable)* |  | |  |
| 27 | IMP Log: Subject Record *(if applicable)* |  | |  |
| 28 | Chain of Custody Log *(if applicable)* |  | |  |
| 29 | Freezer/Refrigerator Temperature Logs *(if applicable)* |  | |  |
| **Investigational Product** | | | | |
| 30 | Confirm that investigational product disposition forms and accountability records are complete and present for all subjects receiving study drug |  |  | |
| 31 | Confirm final disposition of IMPwas completed per site pharmacy protocol, supplier, and sponsor requirements |  |  | |
| **Collected Laboratory Specimens (Samples)** | | | | |
| 32 | Confirm that all specimens have either been analyzed or stored for future use |  |  | |
| 33 | Ensure that specimens collected for future use have been adequately processed, labeled/de-identified, and stored |  |  | |
| 34 | Confirm site process for identification and disposition of future use specimens connected to subjects who withdraw consent or do not consent for their specimens to be saved |  |  | |
| 35 | Confirm destruction, per institutional policies, of specimens not identified for future analysis |  |  | |