|  |
| --- |
| **Investigator and Study Site Close-Out Visit Report** |

**Study Details**

|  |  |
| --- | --- |
| **PO Number:** |  |
| **Study Title:** |  |
| **Principal Investigator:** |  |
| **Site Name and Address** |  |
| **Site ID:** |  |
| **Sponsor:** |  |

**PART 1**

**Visit Summary**

|  |  |
| --- | --- |
| **Date of Close-out Visit(s):** |  |
| **Type of Contact:** | Visit on site: Phone: Other: |
| **Report Produced on:** |  |
| **Follow-up Correspondence Sent:** |  |
| **Study Site Staff Present:** | Name: Position: |
| **Monitor/Sponsor or other representatives Present:** | Name: Position: |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. STUDY/SITE STATUS:** | | | | | | | | | | |
| **Confirm site recruitment status at end of trial (include overall recruitment numbers for site and reason for early closure if applicable).**  Date First patient Screened  Date First Patient Randomised  Date of Last Patient Last Visit  Total Patients Screened (signed ICF)  Total Patients Randomized  Total Patients Participated in data collection  Total Patients Stopped premature (dropouts)  Total number of SAEs | | | | | | | | | | |
| 1. **DATA COLLECTION:** | | | **Yes** | | | **No** | | | | **N/A** |
| **2.1 Has monitoring of CRFs and study documentation been completed as defined in the study specific monitoring plan (if not please indicate reasons for deviation and what proportion of data was monitored)?** | | |  | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | | |
| **2.2 Have all current data queries been resolved?** | | |  | | |  | | | |  |
| **Comments or FU item #:** | | | | | | | | | | |
| **2.3 If this is a multi-centre trial, using paper queries, have all the outstanding queries been sent to the co-ordinating centre?** | | |  | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | | |
| **2.4 Has a provisional timeline for database check and lock been outlined by the Investigator?** | | |  | | |  | | | |  |
| **Comments or FU item #:** | | | | | | | | | | |
| 1. **SAFETY REPORTS:** | | | **Yes** | | | **No** | | | | **N/A** |
| **3.1 Review and finalise all open (S)AE Reports** | | |  | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | | |
| **3.2 Confirm all (S)AEs have been reported to the Sponsor, competent authorities (MHRA) and REC as applicable** | | |  | |  | | | |  | |
| **Comments or FU Item #:** | | | | | | | | | | |
| **3.3 Confirm all SUSARs and safety reports have been submitted to the regulatory authorities** | | |  |  | | | |  | | |
| **Comments of FU Item #:** | | | | | | | | | | |
| **4.0 Investigational Medicinal Product (IMP) and Pharmacy** | | | **Yes** | | | **No** | | | | **N/A** |
| **4.1 Has final IMP accountability been completed (include details of remaining IMP and any discrepancies noted)?** | | |  | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | | |
| **4.2 Have arrangements for the destruction or return of all remaining IMP been confirmed according to the Protocol (include details of Sponsor authorisation and details of destruction if already completed)?** | | |  | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | | |
| **4.3 Have all code break materials been verified (include details of any code that has been broken and verify that if sealed envelopes were used that all seals are intact and that any codes that were broken have been resealed in the correct manner)?** | | |  | | |  | | | |  |
| **Comments or FI Item #:** | | | | | | | | | | |
| **4.4 Has archiving of the Pharmacy File been discussed? Please comment where the file will be archived e.g. amalgamated with the ISF.** | | |  | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | | |
| **5.0 Laboratory and Biological Samples** | | | **Yes** | | | **No** | | | | **N/A** |
| **5.1 Check sample accountability forms are complete** | | |  | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | | |
| **5.2 Ensure all samples have been either shipped/destroyed/on-going storage of any biological samples or other required diagnostic information been documented as applicable (including any duplicate samples)** | | |  | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | | |
| **5.3 Are laboratory certifications and normal ranges filed for the duration of the study?** | | |  | | | |  | | |  |
| **Comments or FU Item #:** | | | | | | | | | | |
| **6.0 Ethics, Regulatory and R&D – SPONSOR** | | | **Yes** | | | **No** | | | | **N/A** |
| **6.1 Has the Investigator submitted the End of Trial Notification to the Ethics Committee (EC) within the correct timelines (for closure of a single site within a multi-site study provide confirmation that the EC have been notified of closure of the site)?** | | |  | | |  | | | |  |
| **Comments or FU Item #:**  **Have all pharmacovigilance reporting requirements to the sponsor, competent authorities and ethics been fulfilled (file a line listing of all SAEs/SUSARs occurring at the site in the ISF. If the site is the co-ordinating site in multi-centre study file a line listing for all SAEs/SUSARs that have occurred in the trial)?**  Date CI/PI informed sponsor/R&D of trial closure or (suspension):  Date CI informed ethics committee (using declaration of end of study report)  Date CI submits end of study report  **For a CTIMP the following should also be submitted**  Date CI submitted the EudraCT form  Date notification was made to the MHRA  Date completed the declaration of end of trial | | | | | | | | | | |
| **6.2 Has the End of Trial Notification been submitted to the Competent Authority (CA) within the correct timelines?** | | |  | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | | |
| **6.3 Has the R&D department been informed of the closure of the site and provided with copies of required documentation?** | | |  | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | | |
|  | **Yes** | | | | **No** | | | | **N/A** |
| **6.4 Have the requirements for providing the Clinical Study Report to the Competent Authority, Ethics and R&D within 12 months of the End of Trial Notification been discussed (include estimated timeline for completion, CI site only)?** |  | | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | |
| **6.5 Have all contractual reporting obligations been fulfilled (include details of what information was required and when it was reported e.g. safety reports & study milestones)?** |  | | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | |
| **7.0 Trial Master File (TMF) / Investigator Site File (ISF)** | **Yes** | | | | **No** | | | | **N/A** |
| **7.1 Has the entire TMF/ISF including Pharmacy File been reviewed to finalise the essential documentation (include details of missing documentation)** |  | | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | |
| **7.2 Has the Principal Investigator signed the completed Delegation of Duties log? The log should cover the entire period of the trial at a site and a scanned signed copy should be collected for filing in the Sponsor File.** |  | | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | |
| **7.3 Are all Curriculum vitae / GCP training information present in the TMF/ISF for all study staff for the duration of the study?** |  | | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | |
| **7.4 Have copies of relevant logs and records been retained for filing in the Sponsor File** |  | | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | |
| **7.5 Accessibility and retention requirements - Have the archiving requirements and responsibilities been discussed with the Investigator? Please ensure that the Investigator is aware that they must inform the sponsor and provide alternative contact details if they leave their current role**  **If the site is archiving, please provide address of facility:** |  | | | |  | | | |  |
| **Comments or FU Item #: Archiving Facility Address:** | | | | | | | | | |
| **7.6 Medical records – accessibility and retention requirements** |  | | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | |
| **8.0 Loaned or Leased Equipment/Study Supplies** | **Yes** | | | | **No** | | | | **N/A** |
| **8.1 Have arrangements been made to return any equipment leased or loaned from the sponsor or any unused study supplies** |  | | | |  | | | |  |
| **Comments or FU Items:** | | | | | | | | | |
| **9.0 Discussion with Investigator for General Close Out Requirements** |  | | | |  | | | |  |
| **9.1 Have you informed the relevant individuals that there is a possibility of further data and documentation queries after site closure?** |  | | | |  | | | | **Yes** | **No** | **N/A** |
| **Comments or FU Item #:** | | | | | | | | | |
| **9.2 Confirm record retention period (including paper and electronic medical records, pharmacy and lab documents, eCRF data)** |  | | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | |
| **9.3 Financial Disclosure (FD) responsibilities, including any changes in FD status** |  | | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | |
| **9.4 Providing individual participant study treatment for blinded trials and documents in medical records if applicable** |  | | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | |
| **9.5 Final Payments – review of any outstanding/pending payments** |  | | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | |
| **9.6 Requirements for regulatory Inspection (MHRA) (if applicable)** |  | | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | |
| **9.7 Investigators are aware of the clinical study report process and publication policies as documented in the study protocol/contracts/agreement** |  | | | | |  | | |  |
| **Comments or FU Item #:** | | | | | | | | | |
| **9.8 Other** | | | | | | | | | |
| **Comments or FU Item #:** | | | | | | | | | |
| **10.0 Site Deactivation** | **Yes** | | | | **No** | | | | **N/A** |
| **10.1 Remove access to the electronic systems** |  | | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | |
| **11.0 Provide a lay summery of the study results to** [**papworth.ppi@nhs.net**](mailto:papworth.ppi@nhs.net) |  | | | |  | | | |  |
| **Comments or FU Item #:** | | | | | | | | | |

**Documents collected during the site closure: None**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |

**Documents filed into the ISF during site closure: None**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |

**Comments: Actions items to be followed up**

|  |  |
| --- | --- |
| **Action Item #** | **Description** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Conclusion:**

**Site Closed Out. All actions completed**

**Site Closed Out. Minor actions pending to be followed up remotely**

**Site Not Closed Out. Major actions pending to be followed up / confirmed at site**

|  |  |
| --- | --- |
| **SIGN OFF**  **Site Monitor:**  **Signature:**  **Date:** |  |

**The finalized TMF/ISF checklist and any supporting information should be provided to the investigator for inclusion in the TMF/ISF prior to archiving.**