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

**Study Details**

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| **PO Number:** |  |
| **Study Title:** |  |
| **Principal Investigator:** |  |
| **Site:** |  |
| **Sponsor:** |  |
| **EUDRACT Number:** |  |

**PART 1**

**Visit Summary**

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| **Date of Close-out Visit(s):** |  |
| **Report Produced on:** |  |
| **Follow-up Correspondence Sent:** |  |
| **Study Site Staff Present:** |  |
| **Monitoring Team Present:** |  |

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| **Study/Site Status** | **Yes** | **No** | **N/A** |
| **1. Confirm site recruitment status at end of trial (include overall recruitment numbers for site and reason for early closure if applicable).** |
|  | **Yes** | **No** | **N/A** |
| **2. 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:** |
| **3. Have all current data queries been resolved?** | **[ ]**  | **[ ]**  | **[ ]**  |
| **Comments:** |
| **4. If this is a multi-centre trial, using paper queries, have all the outstanding queries been sent to the co-ordinating centre?** | **[ ]**  | **[ ]**  | **[ ]**  |
| **Comments:** |
| **5. Has a provisional timeline for database check and lock been outlined by the Investigator?** | **[ ]**  | **[ ]**  | **[ ]**  |
| **Comments:** |
| **6. 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)?** | **[ ]**  | **[ ]**  | **[ ]**  |
| **Comments:** |
| **Investigational Medicinal Product (IMP) and Pharmacy** |
| **7. Has final IMP accountability been completed (include details of remaining IMP and any discrepancies noted)?** | **[ ]**  | **[ ]**  | **[ ]**  |
| **Comments:** |
| **8. 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:** |
| **9. 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:** |
| **10. Has archiving of the Pharmacy File been discussed? Please comment where the file will be archived e.g. amalgamated with the ISF.** | **[ ]**  | **[ ]**  | **[ ]**  |
| **Comments:**  |
|  | **Yes** | **No** | **N/A** |
| **Laboratory and Sampling** |  |  |  |
| **11. Have arrangements for the shipping/destruction/on-going storage of any biological samples or other required diagnostic information been documented?**  | **[ ]**  | **[ ]**  | **[ ]**  |
| **Comments:** |
| **12. Are laboratory certifications and normal ranges filed for the duration of the study?** | **[ ]**  | **[ ]**  | **[ ]**  |
| **Comments:** |
| **13. Have arrangements been made to return any equipment leased or loaned from the sponsor or any unused site supplies** | **[ ]**  | **[ ]**  | **[ ]**  |
| **Comments:** |
| **Ethics, Regulatory and R&D** |  |  |  |
| **14. 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:**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 formDate notification was made to the MHRADate completed the declaration of end of trial |
| **15. Has the End of Trial Notification been submitted to the Competent Authority (CA) within the correct timelines?** | **[ ]**  | **[ ]**  | **[ ]**  |
| **Comments:** |
| **16. Has the R&D department been informed of the closure of the site and provided with copies of required documentation? Note – if this is a CSP study, please ensure that the investigator has informed CSP or similar central facility.** | **[ ]**  | **[ ]**  | **[ ]**  |
| **Comments:** |

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|  | **Yes** | **No** | **N/A** |
| **17. 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:** |
| **18. 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:**  |
| **Trial Master File (TMF) / Investigator Site File (ISF)** |
| **19. Has the entire TMF/ISF including Pharmacy File been reviewed (include details of missing documentation, details of documentation present to be logged on relevant file checklist which will be filed in the TMF/ISF)?** | **[ ]**  | **[ ]**  | **[ ]**  |
| **Comments:** |
| **20. 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:** |
| **21. Are all Curriculum vitae / GCP training information present in the TMF/ISF for all study staff for the duration of the study?** | **[ ]**  | **[ ]**  | **[ ]**  |
| **Comments:** |
| **22. Have copies of the Monitoring Visit Log and other applicable documentation been collected for filing in the Sponsor File (include details of which documents were copied)?** | **[ ]**  | **[ ]**  | **[ ]**  |
| **Comments:**  |
| **General Close Out Requirements** |
| **23. Have you informed the relevant individuals that there is a possibility of further data and documentation queries after site closure?** | **[ ]**  | **[ ]**  | **[ ]**  |
| **Comments:**  |

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| **24. 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.** | **[ ]**  | **[ ]**  | **[ ]**  |
| **Comments:**  |
|  | **Yes** | **No** | **N/A** |
| **25. Have the requirements in case of a regulatory inspection or sponsor audit been discussed?** | **[ ]**  | **[ ]**  | **[ ]**  |
| **Comments:** |
| **27. Review of any outstanding/pending payments** | **[ ]**  | **[ ]**  | **[ ]**  |
| **Comments:** |
| **28. Investigators are aware of the clinical study report process and publication policies as documented in the study protocol/contracts/agreement** | **[ ]**  | **[ ]**  | **[ ]**  |
| **Comments:** |
| **29.** Provide a lay summery of the study results to papworth.ppi@nhs.net |
| **Comments:** |
| **30. Are there any outstanding actions to be completed (provide details and proposed timelines for completion)? \* Complete all outstanding actions in Section 2** | **[ ]**  | **[ ]**  | **[ ]**  |
| **Comments:** |

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|  **Form completed by:**  **Function:**

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| **Date** |  |
|  | **dd/mmm/yy** |

 **Form Reviewed by:** **Function:**

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| **Date** |  |
|  | **dd/mmm/yy** |

 |  **Signature:** **Signature** |

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

**Study Details:**

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| --- | --- |
| **Study Title:** |  |
| **Site Investigator Name:** |  |
| **Department:** |  |
| **Site:** |  |
| **Sponsor(s):** |  |
| **EUDRACT Number:** |  |

**PART 2**

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| --- | --- | --- | --- | --- |
| **Follow Up Actions to be Completed Prior to Archiving** | **Name of Person Responsible for Completing the Task** | **Timeline for Completion of the Task** | **Comments (if applicable)** | **Sign and Date to Confirm that the Task has been Completed** |
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**A copy of Part 2 and any supporting information should be included in the TMF/ISF prior to archiving.**