**Site Closedown Checklist for UoL Sponsored CTIMP Studies**

# Site Information

|  |  |
| --- | --- |
| **Site:** |  |
| **Study Title:** |  |
| **UoL study number:** |  |
| **Centre name:** |  |
| **Investigator:** |  |
| **Date of Visit:** |  |
| **Date of Report** |  |
| **Date Responses due by:** |  |

# List of site and monitoring personnel in attendance

|  |  |
| --- | --- |
| **Name** | **Position** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

# Study Status

|  |  |
| --- | --- |
| Planned patient number |  |
| Number of patients randomised |  |
| Number of patients completed |  |
| Number of patients withdrawn |  |
| Number of patients lost to follow up |  |
| Comments: |  |

# 1. Protocol

| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Is the current approved protocol on file? |  |  |  |  |
| Is the protocol signed and dated? |  |  |  |  |
| Are superseded protocols on file? |  |  |  |  |
| Is there a protocol deviation log on file? |  |  |  |  |
| Have protocol deviations been reported/reviewed by PI? |  |  |  |  |

# 2. Ethics/HRA

| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are all original applications/submissions/approvals on file? |  |  |  |  |
| Are all substantial amendments complete and on file? |  |  |  |  |
| Are all non substantial amendments complete and on file? |  |  |  |  |
| Correspondence on file? |  |  |  |  |
| Notification of trial completion on file? |  |  |  |  |

# 3. Competent Authority

| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are all original applications/submissions/approvals on file? |  |  |  |  |
| Is there CTA acknowledgement of amendment letter/s? |  |  |  |  |
| Notification of trial completion on file? |  |  |  |  |
| MHRA Correspondence on file? |  |  |  |  |

# 4. R&I/ R&D

| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are all original applications/submissions/approvals on file? |  |  |  |  |
| Are all substantial amendment/s complete and on file? |  |  |  |  |
| Are all non substantial amendment/s complete and on file? |  |  |  |  |
| Notification of trial completion on file? |  |  |  |  |
| R&I/R&D Correspondence on file? |  |  |  |  |

# 5. Investigator Site Personnel

| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Is the delegation of authority and signature log updated to reflect end of study? |  |  |  |  |
| Confirm that all CVs/GCP/training records are up to date and on file |  |  |  |  |

# 6. Standard Operating Procedures

| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are the most current SOPs on file? |  |  |  |  |
| Standard Operating Procedures Read List completed for all study team members? |  |  |  |  |

# 7. Study Documentation

| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Is the current approved patient documentation on file? |  |  |  |  |
| Are all superseded patient documents on file? |  |  |  |  |
| Are previous versions of study documentation marked as Superseded? |  |  |  |  |
| Is there a copy of the current Case Report Form  on file? |  |  |  |  |
| Are all superseded Case Report Forms on file? |  |  |  |  |

# 8. Subject Documentation

| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Is there a screening log template on file? |  |  |  |  |
| Is the Subject Screening log complete? |  |  |  |  |
| Is there a Enrolment Log template on file? |  |  |  |  |
| Is the Enrolment Log complete, including an outcome for each subject? |  |  |  |  |

# 9. Randomisation

| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Is there documentation of the Randomisation Process on file? |  |  |  |  |
| Where is the Master Randomisation List held? |  |  |  |  |
| Evidence of correct blinding as per study protocol? |  |  |  |  |

# 10. Informed Consent

| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are all consent forms present and correctly completed? |  |  |  |  |
| Has 100% consent audit been undertaken and documentation of the audit on file? |  |  |  |  |
| Is informed consent process properly documented in the medical/trial records? |  |  |  |  |

# 11. Safety Reporting/Pharmacovigilance

| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are SAE reporting Guidelines/SOP and Pharmacovigilance/Governance contact on file? |  |  |  |  |
| Is there a Current SAE form Template on file? |  |  |  |  |
| Are SAE reports and associated acknowledgement correspondence from Sponsor/R&D on file? |  |  |  |  |
| Have all SAEs been reviewed against the current Reference Safety Information? |  |  |  |  |
| Are SUSAR reporting guidelines on file? |  |  |  |  |
| Are SUSAR reports and associated acknowledgement correspondence from Sponsor/ MHRA/R&D on file? |  |  |  |  |
| Are there signed and dated annual Development Safety Update Report(s) on file? |  |  |  |  |

# 12. Reference Safety Information

| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Have there been any changes to the Reference Safety Information? |  |  |  |  |
| If changes have been made to the reference safety information has a substantial amendment been submitted to the MHRA? |  |  |  |  |
| Is there a current signed and dated Investigator Brochure (IB) on file? |  |  |  |  |
| Are superseded IB brochures on file? |  |  |  |  |
| Is there a current signed and dated Summary of Product Characteristics (SmPC) on file? |  |  |  |  |
| Are Superseded SmPCs on file? |  |  |  |  |
| Are there any Safety alert updates on file? |  |  |  |  |

# 13. Monitoring

| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Is study initiation and subsequent monitoring visit documentation on file? |  |  |  |  |
| Is the study specific monitoring plan on file (UHL CTIMP studies only)? |  |  |  |  |
| Is the monitoring log complete and on file? |  |  |  |  |

# 14. Clinical Laboratory/Specimen Collections

| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Have central Labs been used? |  |  |  |  |
| Are the current and previous Central Lab accreditations on file? |  |  |  |  |
| Are Central Lab normal reference ranges on file? |  |  |  |  |
| Have Local Labs been used? |  |  |  |  |
| Are the Local Laboratory current and previous accreditation certificates on file? |  |  |  |  |
| Are sampling and sample handling procedures documented/is there a lab manual on file? |  |  |  |  |
| Are specimen results reviewed and signed and dated by PI? |  |  |  |  |
| Are specimen results that are out of range marked as clinically significant or not clinically significant? |  |  |  |  |
| Are sample logs/records complete and on file? |  |  |  |  |
| Is there on going storage of samples for future research? |  |  |  |  |
| If yes; Are storage conditions monitored and recorded? |  |  |  |  |
| Have all samples been analysed and destroyed as per protocol? |  |  |  |  |

# 15. Pharmacy

| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are Pharmacy Staff GCP and CVs up to date and on file? |  |  |  |  |
| Is the Delegation of Authority and signature log updated to reflect end of study? |  |  |  |  |
| Are instructions in place with regards to handling trial medication and trial related materials? Dispensing procedure?  Randomization/resupply/returns and destruction?  IMP packaging samples? |  |  |  |  |
| Is there a Pharmacy approved Prescription template on file? |  |  |  |  |
| Records of drug dispensing on file and has the drug been correctly dispensed with all completed prescriptions on file? |  |  |  |  |
| Have drug accountability records been completed? |  |  |  |  |
| Are there adequate collection, recording and maintenance of temperature monitoring records for all locations storing IMPs? |  |  |  |  |
| Have any drug excursions been recorded? |  |  |  |  |
| Have any drug been quarantined? |  |  |  |  |
| Are all required GMP, certificate of analysis and QP release documents on file? |  |  |  |  |

# 16. Financial/Legal agreements

| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are all completed documents relating to contracts, finance, funding, indemnity and sponsorship on file? |  |  |  |  |

# 17. Study Related Supplies

| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are all study related supplies documents completed and on file? |  |  |  |  |
| Are all maintenance and calibration records completed and on file? |  |  |  |  |

# 18. Annual/Final Reports

| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are annual progress and where applicable safety reports to the Ethics Committee on file? |  |  |  |  |
| Are sponsor confirmations of annual report receipt on file? |  |  |  |  |

# 19. Publication

| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are copies of all study analysis publications on file? |  |  |  |  |

# 20. Correspondence

| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Is all study related correspondence on file? |  |  |  |  |

# 21. Source Data Verification

| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are all CRFs complete and all data queries resolved? |  |  |  |  |
| Has all patient identifiable data been removed? |  |  |  |  |
| Confirmation that Data Lock point has been achieved? |  |  |  |  |
| Confirmation that a Statistical Analysis Plan (SAP) is in place? |  |  |  |  |

# 22. Data Protection

| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are computer records and files containing identifiable data stored on a remote and secure server? |  |  |  |  |
| Is the emergency recovery procedure for retrieving data available? |  |  |  |  |
| Is access to electronic study records and files password protected? |  |  |  |  |
| Are electronic data files for analysis anonymised? |  |  |  |  |
| Confirmation that all personal data will be removed according to the timespan stated within the ethical application? |  |  |  |  |
| Is there provision in place for suitable archiving? If yes are details logged with the sponsor? |  |  |  |  |

# 23. Other

| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |

# Additional Comments/Overview

# UoL Site close down Final Outstanding Issues Sign Off

|  |  |
| --- | --- |
| **Sponsor Reference** |  |
| **Study Title:** |  |
| **Date of Visit:** |  |
| **Date of Report** |  |
| **Date Responses due by:** |  |

| **No.** | **Outstanding Issue** | **Action required** | **Action Taken** | **Signature & Date** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
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# Report and Outstanding Action sign off

**Close Down Report Completed By:**

|  |  |
| --- | --- |
| Monitor name: |  |
| e-mail: |  |
| Signature: |  |
| Date: |  |

**Close Down Responses Approved by PI:**

|  |  |
| --- | --- |
| PI Name: |  |
| PI Signature: |  |
| Date: |  |

**Completed Close Down Report Approved by:**

|  |  |
| --- | --- |
| Monitor name: |  |
| Signature: |  |
| Date Close Down Report Closed: |  |