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Number of patients withdrawn	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Are superseded protocols on file?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?				

Comments/Findings

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?				
Comments/Findings				

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?				
Comments/Findings				

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?				
Comments/Findings				

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				
Comments/Findings				

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?				
Comments/Findings				

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Are all superseded patient documents on file?				
Are previous versions of study documentation marked as Superseded?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?				
Comments/Findings				

8. Subject Documentation

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

Comments/Findings

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?				
Comments/Findings				

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?				
Comments/Findings				

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?				

Comments/Findings

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?				
Comments/Findings				

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?				
Comments/Findings				

14. Clinical Laboratory/Specimen Collections

Items Discussed/verified	Yes	No	N/A	
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?				
Comments/Findings				

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?				
Comments/Findings				

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?				
Comments/Findings				

17. Study Related Supplies

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

18. Annual/Final Reports

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

19. Publication

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

20. Correspondence

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

21. Source Data Verification

Items Discussed/verified	Yes	No	N/A	
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?				
Comments/Findings				

22. Data Protection

Items Discussed/verified	Yes	No	N/A	
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?				
Comments/Findings				

23. Other

Items Discussed/verified	Yes	No	N/A	
Comments/Findings				

Additional Comments/Overview

UoL Site close down Final Outstanding Issues Sign Off

Sponsor Reference and Short Title:

Date of Visit: **Date of Report:** **Date Responses Due Back:**

No.	Outstanding Issue	Action required	Action Taken	Signature & Date

Close Down Report Completed By:

Monitor :
Telephone:
e-mail:
Signature:
Date:

Close Down Responses Approved by PI:

PI Name:
PI Signature:
Date:

Completed Close Down Report Approved by:

Monitor :
Signature:
Date Close Down Report Closed: