UNIVERSITY OF LEICESTER

UoL CTIMP Monitoring Visit Report

Site Information

Site :
Study Title:
Sponsor Reference Number:
Centre Name:
Investigator Name:
Date of Visit:
Date of Report:
Date Responses Due Back:

Findings from the monitoring report will be categorised as Critical, Major or Other as SOP S-1016 UoL, Procedure in the event of non-compliance in clinical research. Response to all findings will be required in the format of a CAPA Corrective Action Preventative Action plan. A summary of all findings will be entered into a plan and submitted to the Principal Investigator for action. The CAPA must be returned to the Sponsor within 4 weeks of issue. This requires the CI / PI to explain what action they will take, not necessarily take the action at that point in time. The CAPA will be followed up by the Sponsor until completion/closure.

Critical

- **The safety, well-being or confidentiality of participants has been jeopardised.**
- **Reported data are unreliable or absent.**
- **Inappropriate, insufficient or untimely action has been taken place regarding a major non- compliance.**
- **Where there are a number of Major non-compliances across areas of responsibility, indicating a systematic quality assurance failure.**
- **Provision of the Trial Master File (TMF) does not comply with Regulation 31A 1-3, as the TMF is not readily available or accessible, or the TMF is incomplete to such an extent that it cannot form the basis of inspection and therefore impedes or obstructs inspectors carrying out their duties in verifying compliance with the regulations.**

Major

- **Significant and unjustified non-compliance with relevant legislation or Good Clinical Practice (ICH GCP)**
- **A number of breaches of legislation or GCP within one area, indication quality assurance failure**
- **A failure to comply with legislative requirements including annual reporting requirements**
- **Multiples findings in this category have the potential to escalate to a Critical finding.**

Other

- **Findings that are neither Major nor Critical.**
- **Multiples findings in this category have the potential to escalate to a Major finding.**

Summary/Purpose of Visit

Outstanding Actions from Last Monitoring Visits

List of Site and Monitoring Personnel in Attendance

Name	Position

Study Status

Planned patient number	
Planned recruitment timescale	
Number of patients randomised	
Number of patients on going	
Number of patients completed	
Number of patients withdrawn	
Number of patients ineligible	
Number of patients lost to follow up	
Comments:	

1. Study Team Contacts

Items Discussed/verified	Yes	No	N/A	Comments
Is there a contacts list on file?				
Comments/Findings				

2. 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				

3. Ethics

Items Discussed/verified	Yes	No	N/A	Comments
Is the signed and dated IRAS submission form on file?				
Is the Site Specific Assessment (SSA) form on file?				
Is the Favourable Opinion Letter/HRA Approval on file/ details of Ethics committee constitution?				
Are Substantial Amendments on file?				
Are Non substantial amendments on file?				
Ethics Correspondence on file?				
Comments/Findings				

4. Competent Authority

Items Discussed/verified	Yes	No	N/A	Comments
Is the CTA Application on file?				
Is the CTA Acceptance letter?				
Are CTA Amendment/submission forms on file?				
Is there CTA acknowledgement of amendment letter/s?				
Notice to MHRA of Trial completion on file?				
MHRA Correspondence on file?				
Comments/Findings				

5. R&I

Items Discussed/verified	Yes	No	Comments
Is the Trust Application/Capability Assessment on file?			
Is the Trust Approval/Authorisation on file?			
Are there Substantial Amendment/s on file?			
Are there Non Substantial Amendment/s on file?			
Notification of Trial completion on file?			
Trust Correspondence on file?			
Comments/Findings			

6. Investigator Site Personnel

Items Discussed/verified	Yes	No	N/A	Comments
Is the Delegation of Authority and signature log on file and complete?				
Any changes in staff since last visit?				
Are Original signed and dated CVs on file?				
Is there evidence of GCP training for all staff covering the duration of the study?				
Is there evidence of UHL consent training for all non medics taking consent?				
Comments/Findings				

7. Standard Operating Procedures

Items Discussed/verified	Yes	No	N/A	Comments
Are there Current SOPs on File/staff aware of where to access most current SOPs?				
Standard Operating Procedures Read List completed for all Study team members?				
Comments/Findings				

8. Study Documentation

Items Discussed/verified	Yes	No	N/A	Comments
Is there a copy of the current approved Patient Information Leaflet on file?				
Is there a copy of the current approved Patient Consent Form on file?				
Is there a copy of the current approved Letter of Invitation on file?				
Is there a copy of the current approved GP Letter on file?				

Is there a copy of the current approved Questionnaires, if applicable?				
Is there a copy of the current approved Advert if applicable?				
Other study specific documents reviewed and documented?				
Are previous versions of study documentation marked as Superseded?				
Is there a copy of the current Case Report Form On file?				
Comments/Findings				

9. Subject Documentation

Items Discussed/verified	**Yes**	**No**	**N/A**	**Comments**
Is there a current master copy of the screening log template on file?				
Is the Subject Screening log complete and up to date?				
Is there a current master copy of the Enrolment Log template on file?				
Is the Enrolment Log complete and up to date?				
Comments/Findings				

10. Randomization

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

11. Informed Consent

Items discussed/verified	**Yes**	**No**	**N/A**	**Comments**
Are study staff aware of the correct ethics approved recruitment and consent process?				
Are all consent forms present and correctly completed?				
Have the correct versions of the PIL and consent been used according to the timelines of ethics				

and R&D approval?				
Have study participants been re consented on new PIL information if applicable?				
Has 100% consent audit been undertaken?				
Are copies of the Patient Information Sheet and Consent present in the medical records and TMF/ISF?				
Is informed consent process properly documented in the medical/trial records?				
Comments/Findings				

12. 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 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				

13. 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 (SPC) on file?				
Has there				
Are Superseded SPCs on file?				

Are there any Safety alert updates on file?				
Comments/Findings				

14. Monitoring

Items discussed/verified	**Yes**	**No**	**N/A**	**Comments**
Has an initiation visit taken place?				
Is the Initiation report on file?				
Is the study specific monitoring plan on file (UHL CTIMP studies only)?				
Is the Monitoring Log template on file?				
Is there a completed monitoring log?				
Are all monitoring visit reports on file?				
Pharmacy monitoring report on file if undertaken on separate occasion?				
Comments/Findings				

15. Clinical Laboratory/Specimen Collections

Items Discussed/verified	**Yes**	**No**	**N/A**	
Are central Labs being used?				
Are the current and previous Central Lab accreditations on file?				
Is Central Lab normal reference ranges on file?				
Are Local Labs being used?				
Are the Local Laboratory current and previous accreditation certificates on file?				
Local Lab normal reference ranges				
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 all samples correctly stored in a suitable and secure environment?				
Are sample logs/records held?				
Are Lab kits available and in date?				
Are Sample shipment/ receipt tracking available?				
Are storage conditions monitored and recorded?				
Is there a contingency plan in place for storage facility failure?				

Comments/Findings

16. Pharmacy

Items Discussed/verified	Yes	No	N/A	Comments
Are Pharmacy Staff GCP and CVs up to date and on file?				
Is there a complete and updated pharmacy signature log on file?				
Are instructions in place with regards to handling trial medication and trial related materials. Dispensing procedure Randomization/resupply/returns and destruction?				
Are the current IMP packaging sample labels on file?				
Records of drug dispensing on file and has the drug been correctly dispensed?				
Are drug accountability records being adequately maintained/completed?				
Are their adequate collection, recording and maintenance of temperature monitoring records for all locations storing IMPs?				
Have any drug excursions been recorded				
Has any drug been quarantined?				
Are Expiry/retest dates in accordance with IMP use?				
Is medication compliance checking acceptable?				
Are randomization codes stored appropriately?				
Have any codes been broken?				
Are all required GMP, certificate of analysis and QP release documents on file?				
Is there a Pharmacy approved Prescription template on file?				
Is all completed prescription on file?				
Comments/Findings				

17. Financial/Legal agreements

Items Discussed/verified	Yes	No	N/A	Comments
Are contracts in place with all Investigators and sub-contractors? Clinical Agreements etc.?				
Is confirmation of sponsorship on file?				

Is funding documentation on file?				
Are Insurance/Indemnity statements on file?				
Is Financial Correspondence on file?				
Are there Records of subject expenses?				
Comments/Findings				

18. Study Related Supplies

Items Discussed/verified	**Yes**	**No**	**N/A**	
Are shipment and delivery records on file?				
Is collection and return of equipment documented and on file?				
Are supply reorder form templates on file?				
Are completed supply request forms on file?				
Are records kept and retained for maintenance, calibration and validation of all equipment used as part of the study?				
Comments/Findings				

19. 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?				
Is their evidence of notification of trial completion to Sponsor, REC, Competent Authority and R&D?				
Comments/Findings				

20. Publication

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

21. Correspondence

Items Discussed/verified	**Yes**	**No**	**N/A**	
Are Meeting agendas and minutes on file?				
Are copies of study newsletters on file?				
Are copies of all correspondence between the Chief Investigator and collaborating centres on file (multicentre studies only?				

Is general study related correspondence on file?				
Comments/Findings				

22. Source Data Verification

Items Discussed/verified	**Yes**	**No**	**N/A**	
Are all source documents available to verify the data in the Case Report Form?				
Is the CRF completion timely and accurate?				
Have all CRF data queries resolved since previous visit?				
Has SDV been performed according to the monitoring plan?				
Location of source documents				
Is the Statistical Analysis Plan (SAP) in place? (Required before database lock)				
Comments/Findings				

23. Data Protection

Items Discussed/verified	**Yes**	**No**	**N/A**	
Is all study hard copy documentation stored in a restricted access area?				
Are all study related documentation designed to ensure that they are anonymised by the use of study patient identifier?				
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?				
Will any documentation be archived off site If yes are details logged with the Sponsor?				
Where a data access/sharing agreement exists (e.g. with HSCIC), has the data been accessed in accordance with the terms & conditions of the agreement?				
Comments/Findings				

24. Other

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

Monitoring Visit Response Document for UoL.....

Monitoring visit Date: **Monitoring visit report date:** **Date response required:**

No	Category	Finding	Immediate/ Corrective Action	Preventative Action	Completed by Initials & Date Completed

Monitoring Report Completed By:

Monitor :
Telephone
e-mail:
Signature:
Date:

Completed Responses Approved by PI:

PI Name:
PI Signature:
Date:

Completed Monitoring Report Approved by:

Monitor :
Signature:
Date Monitoring Report Closed: