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UoL Site Initiation Checklist – CTIMP Studies

1. Site Information

Site	**Initiation Visit Method**
Sponsor Reference Number:	On Site ☐
Study Name:	Teleconference ☐
R&I/ R&D Reference Number:	Other (specify) ☐
Investigator:	
Study Site:	
Date of Initiation:	
Conducted by:	

2. Personnel in Attendance

Name	Title

3. Study Overview/Protocol Overview

Items discussed/verified	Comments
Background and purpose of study	
Study IMP/s	

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4. GCP and Regulatory Compliance

Items Discussed/verified	Yes	No	Comments
Investigator obligations			
Sponsor obligations			
Standard Operating Procedures			
Ethics reporting requirements			
MHRA reporting requirements			
Sponsor reporting requirements			
Amendments			
Annual reports/DSUR Requirements			
Data Protection			
Study record storage requirements			
Archiving arrangements			

5. Trial Master File/Investigator Site File

Items Discussed/verified	Yes	No	Comments
TMF/ISF created and complete			
Delegated Individual for TMF/ISF maintenance			
Secure Location/limited Access			

6. Study Approval Status/Essential Documents

Items Discussed/verified	Yes	No	Version/ Comments
MHRA Approval			
EC Favourable opinion/HRA approval			
Composite of EC committee			
R&D/R&I Approval			
Signed Sponsor/CI Agreement			
Signed Financial Agreement			
Indemnity/Insurance			
Approved Reference Safety Information (RSI): Investigator Brochure/SmPC			
Protocol (+ protocol signed by PI?)			
Protocol deviation/Serious Breach reporting			
Patient Information Leaflet			
Consent			
Patient Invitation			
GP Letter			
Advertisement			
CRF			
Other: Have any contact numbers on PIS been checked?			

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7. Investigator Site Personnel

Items Discussed/verified	Yes	No	Comments
Adequate site staff to conduct the study			
Signed and dated CV for all study team members			
Documented evidence of GCP Training/study specific training			
All study team members listed on Delegation of duties log			

8. Recruitment

Items discussed/verified	Yes	No	Comments
Planned Number of Trial subjects			
Methods for identifying Subjects			
Requirement to complete Subject Screening and Enrolment logs			
Procedure for withdrawn Subjects/Lost to follow-up			
Randomisation Process			

9. Informed Consent/Enrolment

Items Discussed/verified	Yes	No	Comments
Informed consent procedures/documentation requirements			
Eligibility criteria			
100% consent audit requirements			
Randomisation procedures			

10. Investigational Medicinal Products

Items discussed/verified	Yes	No	Comments
QP release document			
Certificate of analysis			
Receipt			
Labelling and packaging			
Storage requirements			
Dispensing procedures			
Drug accountability			
Return of IMP procedures			
Reordering procedures			
Drug Destruction			
Unblinding procedure/code break envelopes			

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11. Safety Reporting/Pharmacovigilance

Items Discussed/verified	Yes	No	Comments
AE / SAE reporting procedures			
SUSAR reporting procedures			
Notification process			
Urgent Safety Measures			
Data Safety Monitoring Board meeting and reporting requirements			

12. Data Collection

Items Discussed/verified	Yes	No	Comments
Format and timelines			
CRF completion guidelines			
Queries and corrections			
eDC training			
File notes			
Statistical Analysis Plan			

13. Source Documentation

Items Discussed/verified	Yes	No	Comments
Source Data agreement			
CRFs as source			
Document retention			

14. Equipment List

Items Discussed/verified	Yes	No	Comments
Equipment list			
Calibration of equipment			
Maintenance/service record requirements			

15. Specimen collection

Items Discussed/verified	Yes	No	Comments
Specimen Collection			
Sample result verification/CS/NCS status and required actions			
Specimens to be obtained			
Specimen Storage			
Specimen storage and tracking logs			
Temperature monitoring			
Sample shipment			
Laboratory training/manual/SOPs			
Lab kits			
Lab Accreditation			
Lab Normal Values			

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16. Communications

Items discussed/verified	Yes	No	Comments
Format and frequency			
Site contacts			
Recruitment updates to sponsor			

17. Monitoring

Items discussed/verified	Yes	No	Comments
Site monitoring Plan			
Site Monitoring response requirements			

18. SOP

Items discussed/verified	Yes	No	Comments
Are the most current SOPs on file or do the study team know how to access the sponsor SOPs via the webpages?			
SOP Read By List completed for all study team members?			

19. Archiving

Items discussed/verified	Yes	No	Comments
Archiving at end of study discussed?			

Additional Comments/ Visit Overview

Study commencement must not occur until Sponsor Green Light process has been completed

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UoL Site Initiation Outstanding Issues Report

Sponsor Reference and Short Title:

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

No	Outstanding Issue	Action required	Action Taken	Signature & Date

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SIV Report Completed By:

Monitor:
Telephone
e-mail:
Signature:
Date:

Completed Responses Approved by PI:

PI Name:
PI Signature:
Date:

Completed SIV Report Approved By:

Monitor:
Signature:
Date: