**UHL Site Initiation Checklist for CTIMP Studies**

**1. Site Information**

|  |  |
| --- | --- |
| **Site**  | **Initiation Visit Method** |
| Sponsor Reference Number: | On Site 🞏 |
| Study Name: | Teleconference 🞏 |
| Investigator: | Other (specify) 🞏 |
| 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) |  |

**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/ Annual Safety Report |[ ] [ ]   |
| Data Protection/ GDPR |[ ] [ ]   |
| 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 |[ ] [ ]   |
| REC favourable opinion/HRA approval |[ ] [ ]   |
| Composite of REC committee |[ ] [ ]   |
| R&D/R&I Capacity & Capability |[ ] [ ]   |
| Signed Sponsor/CI agreement |[ ] [ ]   |
| Signed financial agreement/ contract |[ ] [ ]   |
| Indemnity/Insurance |[ ] [ ]   |
| Approved reference safety information: Investigator Brochure/SmPC |[ ] [ ]   |
| Protocol (+ protocol signed by CI/PI/Sponsor) |[ ] [ ]   |
| Protocol deviation/Serious breach reporting |[ ] [ ]   |
| Patient information leaflet/ sheet(document version no. and date) |[ ] [ ]   |
| Contact numbers on patient information leaflet/ sheet been checked? |[ ] [ ]   |
| Consent(document version no. and date) |[ ] [ ]   |
| Patient invitation(document version no. and date) |[ ] [ ]   |
| GP letter(document version no. and date) |[ ] [ ]   |
| Advertisement(document version no. and date) |[ ] [ ]   |
| CRF(document version no. and date) |[ ] [ ]   |
| ARSAC License |[ ] [ ]   |
| Other |[ ] [ ]   |
| Schedule of Source Data (SOP S-1007) completed |[ ] [ ]   |

**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 for all study team members |[ ] [ ]   |
| All study team members listed on delegation of authority & signature log; all entries signed and dated by PI |[ ] [ ]   |

**8. Recruitment**

|  |  |  |  |
| --- | --- | --- | --- |
| Items discussed/verified | Yes | No | Comments |
| Planned number of trial subjects |[ ] [ ]   |
| Methods for identifying subjects |[ ] [ ]   |
| Requirement to complete subject screening logs  |[ ] [ ]   |
| Requirement to complete subject enrolment logs  |[ ] [ ]   |
| Procedure for withdrawn subjects/lost to follow-up |[ ] [ ]   |

**9. Informed Consent/Enrolment/Randomisation**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comments |
| Informed consent procedures/documentation requirements |[ ] [ ]   |
| Eligibility criteria |[ ] [ ]   |
| Consent audit requirements, per study risk strategy |[ ] [ ]   |
| Randomisation procedures |[ ] [ ]   |
| Unblinding procedure/ code break envelopes |[ ] [ ]   |
| Which team members are blinded/ unblinded |[ ] [ ]   |

**10. Investigational Medicinal Products**

|  |  |  |  |
| --- | --- | --- | --- |
| Items discussed/verified | Yes | No | Comments |
| QP release document |[ ] [ ]   |
| Certificate of analysis |[ ] [ ]   |
| Receipt |[ ] [ ]   |
| Labelling and packaging |[ ] [ ]   |
| Storage requirements |[ ] [ ]   |
| Dispensing procedures |[ ] [ ]   |
| IMP accountability |[ ] [ ]   |
| Return of IMP procedures |[ ] [ ]   |
| Reordering procedures |[ ] [ ]   |
| Drug destruction |[ ] [ ]   |

**11. Safety Reporting/Pharmacovigilance**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comments |
| AE / SAE reporting procedures |[ ] [ ]   |
| SUSAR reporting procedures |[ ] [ ]   |
| eSUSAR access |[ ] [ ]   |
| Notification process |[ ] [ ]   |
| Urgent Safety Measures |[ ] [ ]   |
| DSUR /Short format DSUR  |[ ] [ ]   |
| Data safety monitoring board/ committee meeting and reporting requirements |[ ] [ ]   |

**12. Data Management**

|  |  |  |  |
| --- | --- | --- | --- |
| **Items Discussed/verified** | Yes | No | Comments |
| Format and timelines |[ ] [ ]   |
| CRF completion guidelines |[ ] [ ]   |
| Are all study related documentation designed to ensure that they are anonymised by the use of study patient identifier |[ ] [ ]   |
| Is all study hard copy documentation stored in a restricted access area |[ ] [ ]   |
| Is access to electronic study records and files password protected?  |[ ] [ ]   |
| Are computer records and files containing identifiable data stored on a remote and secure server? Are emergency recovery processes in place? |[ ] [ ]   |
| Requirements for Queries and corrections resolution  |[ ] [ ]   |
| eDC training (for electronic case report forms) |[ ] [ ]   |
| Are electronic data files for analysis anonymised? |[ ] [ ]   |
| Data Management plan in place (If applicable) |[ ] [ ]   |
| Statistical analysis plan requirements |[ ] [ ]   |

**13. Source Documentation**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comments |
| Source data agreement/ schedule |[ ] [ ]   |
| CRFs as source |[ ] [ ]   |
| Document retention period |[ ] [ ]   |
| Archiving responsibilities at end of study |[ ] [ ]   |

**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 reference ranges |[ ] [ ]   |

**16. Communications**

|  |  |  |  |
| --- | --- | --- | --- |
| Items discussed/verified | Yes | No | Comments |
| Format and frequency |[ ] [ ]   |
| Site contacts |[ ] [ ]   |
| Recruitment updates to Sponsor/ EDGE/ CPMS |[ ] [ ]   |

**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 list completed for all study team members?  |[ ] [ ]   |

**Additional Comments/ Visit Overview**

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

UHL 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 Completed By:**

|  |
| --- |
| Name:  |
| Role:  |
| Telephone:  |
| e-mail:  |
| Signature:  |
| Date:  |

 **Report Responses Completed By:**

|  |
| --- |
| Name:  |
| Telephone:  |
| e-mail:  |
| Signature:  |
| Date:  |

**Completed Responses Approved by PI:**

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

**Completed SIV Report Approved/ Closed By:**

|  |
| --- |
| Name:  |
| Role:  |
| Signature:  |
| Date:  |