**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: |