|  |
| --- |
| **SPONSOR FILE REPORT TEMPLATE** |
| **P0 No.****EudraCT No** | P0XXXX | **Study Title:** |  |
| **Investigator** |  | **Monitor(s)** |  |
| **Site Name** |  | **Site Number** |  |
| **Date of Visit** |  | **Site Staff** **Present** |  |
| **RECRUITMENT STATUS** |
| **No. patients** **screened:**  | **No. patients****consented:**  | **No. participants****randomised:** | **Recruitment** **Target:** |
| ***e-Sponsor File Index*** |
| **SECTION** | ***Essential Documents*** |
| **ITEM** | Version control logContact details sheetList of applicable SOPs for the study |
| **Comments** |  |
| **Action Required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***0.1 Sponsor file structure and QC*** |
| **ITEM** |  |
| **Comments** |  |
| **Action Required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***0.2 Study wide protocol non-compliance*** |
| **ITEM** |  |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***0.3 Study wide recruitment*** |
| **ITEM** |  |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***0.4 Superseded Documents*** |
| **ITEM** |  |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***1.0 Trial specific documentation*** |
| **ITEM** | Current approved Protocol with signatures *(Held in the paper file)*Approved Patient Information Sheet (PIS)Informed Consent FormLetter of InterestGP LetterClinical Study Report* 1. **File notes**
	2. **Correspondence**
	3. **Superseded documents**
 |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***2.0 Sponsorship*** |
| **ITEM** | Peer reviewSponsor Risk AssessmentSponsorship Delegation LogProject Management Delegation Log**2.1 Acceptance of sponsorship and RGPAS****2.2 Correspondence****2.3 Superseded Documents** |
| **Comments** |  |
| **Action Required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***3.0 Sponsor Oversight of Sites*** |
| **ITEM** | **3.1 Site X** (only applicable to multi-centre studies – Check CV’s, GCP, pertinent documents, correspondence demonstrating sponsor oversight)3.1.1 Site Delegation log3.1.2 CV’s and GCP certificates3.1.3 Local Approval Documents (C&C)3.1.4 Executed contract and costings *(Held in the paper file)*3.1.5 Localised PIS/ICF3.1.6 Lab Ranges3.1.7 Evidence of training3.1.8 Local information pack3.1.9 Correspondence with site |
| **Comments** |  |
| **Action Required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***4.0 Finance and Indemnity*** |
| **ITEM** | Funding agreement letterIndemnity certification/policyInsurance documents**4.1 Costings****4.2 Study Level Contracts** *(Held in the paper file)***4.3 Correspondence****4.4 Superseded documents** |
| **Comments** |  |
| **Action Required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***5.0 Grants*** |
| **ITEM** | Outline applicationFull grant applicationAward letter**5.1 Study progress reports****5.2 Correspondence****5.3 Superseded Documents** |
| **Comments** |  |
| **Action Required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***6.0 Ethics and HRA*** |
| **ITEM** | Declaration of End of Trial notification form sent to Ethics**6.1 Original Ethics application****6.2 Favourable Ethical Approval letter(s)****6.3 HRA Approval Letter(s)****6.4 Adoption onto the NIHR Portfolio****6.5 Amendments Documentation****6.6 Annual Progress Report(s) to Ethics****6.7 Correspondence with Ethics****6.8 Correspondence with HRA****6.9 Correspondence re Ethics and HRA****6.10 Superseded Documents** |
| **Comments** |  |
| **Action Required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***7.0 MHRA*** |
| **ITEM** | EudraCT NumberDeclaration of end of trial notification form sent to MHRA**7.1 Original MHRA Application****7.2 Clinical Trial Authorisation (CTA) Letter(s)****7.3 Amendments Documentation****7.4 DSUR****7.5 Correspondence****7.6 Superseded Documents** |
| **Comments** |  |
| **Action Required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***8.0 Safety*** |
| **ITEM** | Blank/template SAE form**8.1 safety reports****8.2 SUSAR reports****8.3 Urgent Safety Measures documentation****8.4 Copies of notifications to investigators of safety information****8.5 Correspondence****8.6 Superseded Documents** |
| **Comments** |  |
| **Action Required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***9.0 Pharmacovigilance*** |
| **ITEM** | Investigators Brochure (IB) and / or summary of Product Characteristics (SmPC) and updatesProcedure for randomisation, unblinding and code break**9.1 RSI****9.2 Details of any code break procedure testing****9.3 Details of any code breaks****9.4 Correspondence****9.5 Superseded Documents** |
| **Comments** |  |
| **Action Required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***10.0 Pharmacy*** |
| **ITEM** | Quality AgreementClinical Trial PrescriptionPharmacy manualSample of label**10.1 QA Documents****10.2 Sub-contracting documents****10.3 Drug Shipment****10.4 Drug recall and Quarantine Incidents****10.5 Correspondence****10.6 Superseded Documents** |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***11.0 Data Management*** |
| **ITEM** | Data Management planData Validation planUser access spreadsheet**11.1 Sub-contracting documents****11.2 Data Management Approval forms****11.3 CRF Design change Form(s)****11.4 Data Amendment Form(s)****11.5 Blank case report forms (CRFs) and data collection instruments****11.6 Data imports****11.7 Data transfers****11.8 Data completion reviews****11.9 CDM Design and Programming****11.10 Correspondence****11.11 Superseded Documents** |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***12.0 Statistics*** |
| **ITEM** | Statistical Analysis planHealth Economics Analysis PlanRandomisation ScheduleRandomisation Allocation List**12.1 Sub-contracting documents****12.2 Correspondence****12.3 Superseded Documents** |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***13.0 Monitoring*** |
| **ITEM** | Monitoring planClose down report**13.1 Monitoring reports****13.2 Audit reports****13.3 Correspondence****13.4 Superseded Documents** |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***14.0 Meetings*** |
| **ITEM** | Study Action Item Tracker and Study Decision Log**14.1 Study Team Meetings****14.2 Trial Steering committee meetings****14.3 Data Monitoring committee Meetings****14.4 Investigators Meeting(s)****14.5 Site initiation Meeting(s)****14.6 Correspondence****14.7 Superseded Documents** |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***15.0 Laboratory*** |
| **ITEM** | Pathology registration formNormal Values/rangesSample list – Record of retained tissue/body samples (if any)Material Transfer AgreementTissue bank application form**15.1 Lab Accreditation certificates****15.2 Lab Manual(s)****15.3 Sub-contracting documents****15.4 Correspondence****15.5 Superseded Documents** |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***16.0 Publications*** |
| **ITEM** | **16.1 Correspondence****16.2 Superseded Documents** |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***17.0 COVID-19 Pandemic*** |
| **ITEM** | **17.1 COVID-19 Impact Documents****17.2 Correspondence****17.3 Superseded Documents** |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |

|  |
| --- |
| **SUMMARY OF ACTION POINTS – please state who is to action and by when** |
|  |

Monitor’s Name:

Monitor’s Signature:

Date:

Principle Investigator’s Name:

Principal Investigator’s Signature:

Date: