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| **TPL010 SPONSOR FILE INDEX REPORT TEMPLATE** |
| **P0 No.** | P0XXXX | **Study Title:** |  |
| **PI**  |  | **Monitor(s)** |  |
| **Site Name** |  | **Site ID**  |  |
| **Date of Visit** |  | **Site Staff** **Present** |  |
| **RECRUITMENT STATUS** |
| **No. patients** **screened:**  | **No. patients****consented:**  | **No. participants****randomised:** | **Recruitment** **Target:** |
|  |
| **SECTION** | ***Essential Documents*** |
| **ITEM** | Version control logContact details sheetList of applicable SOPs for the study |
| **Comments** |  |
| **Action Required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***1.0 Sponsor File Structure and Index Check***  |
| **ITEM** |  |
| **Comments** |  |
| **Action Required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***2.0 Study Wide Protocol Non-Compliance*** |
| **ITEM** | **2.1 Protocol Non-Compliance Forms****2.2 Protocol Non-Compliance Reports****2.3 Correspondence****2.4 Superseded Documents** |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***3.0 Study Wide Recruitment*** |
| **ITEM** | **3.1 Study level screening and recruitment logs****3.2 Recruitment Review Meetings****3.3 Correspondence** |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***4.0 Superseded Documents*** |
| **ITEM** |  |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***5.0 Trial Specific Documentation*** |
| **ITEM** | Clinical Study Report5.1 Protocol 5.2 (PIS/ICF)5.3 Letters* 1. Advertisement Materials

5.5 Other study documents5.6 File notes5.7 Correspondence5.8 Superseded Documents |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***6.0 Sponsorship*** |
| **ITEM** | Peer reviewSponsor Risk AssessmentSponsorship Delegation LogProject Management Delegation Log**6.1 Acceptance of sponsorship and RGPAS****6.2 Sponsor Reports****6.3 Sponsor Training Records****6.4 Correspondence****6.5 Superseded Documents** |
| **Comments** |  |
| **Action Required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***7.0 Sponsor Oversight of Sites*** |
| **ITEM** | Site Tracker**7.1 Site Feasibility and Selection****7.2 All Site Communications****7.3 Site X** 7.3.1. Site Delegation Log7.3.2 CV’s and GCP Certificates7.3.3 Local Approval Documents (C&C)7.3.4 Executed Contract and Costings *(Held in the paper file)*7.3.5 Localised Documents 7.3.6 Laboratory Documents7.3.7 Evidence of Training7.3.8 Local Information Pack7.3.9 Monitoring 7.3.10 Recruitment7.3.11 Correspondence with Site |
| **Comments** |  |
| **Action Required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***8.0 Finance and Insurance/Indemnity*** |
| **ITEM** | Funding agreement letter**8.1 Costings****8.2 Study Level Contracts** *(Held in the paper file)***8.4 Invoicing****8.5 Correspondence****8.6 Superseded documents** |
| **Comments** |  |
| **Action Required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***9.0 Grants*** |
| **ITEM** | **9.1 Grant Applications and Award Documents****9.2 Study Progress Reports****9.3 Correspondence****9.4 Superseded Documents** |
| **Comments** |  |
| **Action Required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***10.0 Ethics and HRA*** |
| **ITEM** | Declaration of End of Trial notification form sent to Ethics**10.1 Combined Review Original Application****10.2 Favourable Ethical Approval letter(s)****10.3 HRA Approval Letter(s)****10.4 Adoption onto the NIHR Portfolio****10.5 Amendments Documentation****10.6 Correspondence with Ethics****10.7 Correspondence with HRA****10.8 Correspondence re Ethics and HRA****10.9 Superseded Documents** |
| **Comments** |  |
| **Action Required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***11.0 MHRA*** |
| **ITEM** | Declaration of end of trial notification form sent to MHRA**11.1 Original MHRA Application****11.2 Clinical Trial Authorisation (CTA) Letter(s)****11.3 Amendments Documentation****11.4 DSUR****11.5 Correspondence****11.6 Superseded Documents** |
| **Comments** |  |
| **Action Required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***12.0 Safety*** |
| **ITEM** | Blank/template SAE formProcedure for randomisation, unblinding and code break**12.1 safety reports****12.2 SUSAR/USADE reports****12.3 Urgent Safety Measures Documentation****12.4 Copies of notifications to investigators of safety information****12.5 Details of any code break procedure testing****12.6Details of any code breaks****12.7 Correspondence****12.8 Superseded Documents** |
| **Comments** |  |
| **Action Required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***13.0 Pharmacovigilance*** |
| **ITEM** | Investigators Brochure (IB) and / or Summary of Product Characteristics (SmPC) and updates**13.1 RSI****13.2 Correspondence****13.3 Superseded Documents** |
| **Comments** |  |
| **Action Required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***14.0 Pharmacy*** |
| **ITEM** | Quality AgreementClinical Trial PrescriptionPharmacy manualSample of label**14.1 QA Documents****14.2 Sub-contracting documents****14.3 Drug Shipment****14.4 Drug recall and Quarantine Incidents****14.5 Correspondence****14.6 Superseded Documents** |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***15.0 Data Management*** |
| **ITEM** | Data Management PlanData Validation Specification User Access Spreadsheet**15.1 Sub-contracting Documents****15.2 Data Management Approval forms****15.3 CRF Design change Form(s)****15.4 Data Amendment Form(s)****15.5 Blank Case Report Forms (CRFs) and Data Collection Instruments****15.6 Data Imports****15.7 Data Transfers****15.8 Data completion reviews****15.9 CDM Design and Programming****15.10 Archived Database****15.11 Correspondence****15.12 Superseded Documents** |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***16.0 Statistics and Analysis*** |
| **ITEM** | Statistical Analysis planHealth Economics Analysis PlanRandomisation ScheduleRandomisation Allocation List**16.1 Sub-contracting documents****16.2 Mock Reports****16.3 Correspondence****16.4 Superseded Documents** |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***17.0 Monitoring*** |
| **ITEM** | Monitoring plan**17.1 Audit reports****17.2 Correspondence****17.3 Superseded Documents** |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***18.0 Meetings*** |
| **ITEM** | Study Action Item Tracker and Study Decision Log**18.1 Study Team Meetings****18.2 Trial Steering committee meetings****18.3 Data Monitoring committee Meetings****18.4 Investigators Meeting(s)****18.5 Site initiation Meeting(s)****18.6 PPI Meeting(s)****18.7 Correspondence****18.8 Superseded Documents** |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***19.0 Laboratory*** |
| **ITEM** | Pathology registration formNormal Values/rangesSample list – Record of retained tissue/body samples (if any)Material Transfer AgreementTissue bank application form**19.1 Lab Accreditation certificates****19.2 Lab Manual(s)****19.3 Sub-contracting documents****19.4 Correspondence****19.5 Superseded Documents** |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***20.0 Publications*** |
| **ITEM** | **20.1 Publication Plan****20.2 Dissemination Plan****20.3 Journal Publications****20.4 Press Release and Other Media****20.5 Newsletters****20.6 Correspondence****20.7 Superseded Documents** |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |
| **SECTION** | ***21.0 Equipment and Devices*** |
| **ITEM** | Instructions for useDevice Tracker**21.1 User Manuals****21.2 Shipping Records****21.3 Storage Records****21.4 Calibration Records****21.5 Correspondence****21.6 Superseded Documents** |
| **Comments** |  |
| **Action required** |  |
| **CTC/CTA comment** |  |

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| **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: