|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **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 log  Contact details sheet  List 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| | **2.1 Protocol Non-Compliance Forms**  **2.2 Protocol Non-Compliance Reports**  **2.3 Correspondence**  **2.4 Superseded Documents** | | | | | |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| **SECTION** | | ***4.0 Superseded Documents*** | | | | | |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 Report  5.1 Protocol  5.2 (PIS/ICF)  5.3 Letters   * 1. Advertisement Materials   5.5 Other study documents  5.6 File notes  5.7 Correspondence  5.8 Superseded Documents | | | | | |
| **Comments** | |  | | | | | |
| **Action required** | |  | | | | | |
| **CTC/CTA comment** | |  | | | | | |
| **SECTION** | | ***6.0 Sponsorship*** | | | | | |
| **ITEM** | | Peer review  Sponsor Risk Assessment  Sponsorship Delegation Log  Project 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 Log  7.3.2 CV’s and GCP Certificates  7.3.3 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 Documents  7.3.7 Evidence of Training  7.3.8 Local Information Pack  7.3.9 Monitoring  7.3.10 Recruitment  7.3.11 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 form  Procedure 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 Agreement  Clinical Trial Prescription  Pharmacy manual  Sample 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 Plan  Data 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 plan  Health Economics Analysis Plan  Randomisation Schedule  Randomisation 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 form  Normal Values/ranges  Sample list – Record of retained tissue/body samples (if any)  Material Transfer Agreement  Tissue 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 use  Device 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: