|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **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 log  Contact details sheet  List 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| **SECTION** | | ***0.4 Superseded Documents*** | | | | | |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 Form  Letter of Interest  GP Letter  Clinical Study Report   * 1. **File notes**   2. **Correspondence**   3. **Superseded documents** | | | | | |
| **Comments** | |  | | | | | |
| **Action required** | |  | | | | | |
| **CTC/CTA comment** | |  | | | | | |
| **SECTION** | | ***2.0 Sponsorship*** | | | | | |
| **ITEM** | | Peer review  Sponsor Risk Assessment  Sponsorship Delegation Log  Project Management Delegation Log  **2.1 Acceptance of sponsorship and RGPAS**  **2.2 Correspondence**  **2.3 Superseded Documents** | | | | | |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 log  3.1.2 CV’s and GCP certificates  3.1.3 Local Approval Documents (C&C)  3.1.4 Executed contract and costings *(Held in the paper file)*  3.1.5 Localised PIS/ICF  3.1.6 Lab Ranges  3.1.7 Evidence of training  3.1.8 Local information pack  3.1.9 Correspondence with site | | | | | |
| **Comments** | |  | | | | | |
| **Action Required** | |  | | | | | |
| **CTC/CTA comment** | |  | | | | | |
| **SECTION** | | ***4.0 Finance and Indemnity*** | | | | | |
| **ITEM** | | Funding agreement letter  Indemnity certification/policy  Insurance 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 application  Full grant application  Award 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 Number  Declaration 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 updates  Procedure 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 Agreement  Clinical Trial Prescription  Pharmacy manual  Sample 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 plan  Data Validation plan  User 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 plan  Health Economics Analysis Plan  Randomisation Schedule  Randomisation 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 plan  Close 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 form  Normal Values/ranges  Sample list – Record of retained tissue/body samples (if any)  Material Transfer Agreement  Tissue 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** | |  | | | | | |

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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: