|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **SITE FILE REPORT TEMPLATE** | | | | | | | | | |
| **P0 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-Site File Index*** | | | | | | | | | |
| **SECTION** | | | ***Version Control Log*** | | | | | | |
| **Comments** | | |  | | | | | | |
| **Action required** | | |  | | | | | | |
| **CTC/CTA comment** | | |  | | | | | | |
| **SECTION** | | ***0.1 site file structure and QC*** | | | | | | | |
| **comments** | |  | | | | | | | |
| **Action required** | |  | | | | | | | |
| **CTC/CTA comment** | |  | | | | | | | |
| **SECTION** | | ***1.0 Trial Specific Documentation*** | | | | | | | |
| **ITEM** | | Current approved protocol with signatures *(Held in the paper file)*  Clinical Study Report   * 1. **File Notes**   2. **Correspondence**   3. **Superseded Documents** | | | | | | | |
| **Comments** | |  | | | | | | | |
| **Action Required** | |  | | | | | | | |
| **CTC/CTA comment** | |  | | | | | | | |
| **SECTION** | | ***2.0 Site Documentation*** | | | | | | | |
| **ITEM** | | Site Agreement *(Held in the paper file)*  Site Delegation Log *(Held in the paper file)*  Site Training Log *(Held in the paper file)*   * 1. **Localised (site specific) Documents**   2. **Study Staff Training Documentation** *(held in the paper file)*   3. **Finance**   4. **Correspondence**   5. **Superseded Documents** | | | | | | | |
| **Comments** | |  | | | | | | | |
| **Action Required** | |  | | | | | | | |
| **CTC/CTA comment** | |  | | | | | | | |
| **SECTION** | | ***3.0 Recruitment*** | | | | | | | |
| **ITEM** | | **3.1 Screening / enrolment log** *(Held in the paper file)*  **3.2 Signed Informed consent forms** *(Held in the paper file)*  **3.3 Correspondence**  **3.4 Superseded Documents** | | | | | | | |
| **Comments** | |  | | | | | | | |
| **Action Required** | |  | | | | | | | |
| **CTC/CTA comment** | |  | | | | | | | |
| **SECTION** | | ***4.0 Evidence of Ethics/HRA and Regulatory approvals*** | | | | | | | |
| **ITEM** | | **4.1 Evidence of Ethics Approval**   * 1. **Evidence of HRA Approval**   2. **Evidence of Regulatory Approval**   3. **Amendments Documentation**   4. **Correspondence**   5. **Superseded Documents** | | | | | | | |
| **Comments** | |  | | | | | | | |
| **Action Required** | |  | | | | | | | |
| **CTC/CTA comment** | |  | | | | | | | |
| **SECTION** | | ***5.0 Safety*** | | | | | | | |
| **ITEM** | | Blank / template SAE form   * 1. **Adverse event reports**   2. **SAE reports**   3. **Details of protocol non-compliance**   4. **Safety information notifications from Sponsor**   5. **Correspondence**   6. **Superseded Documents** | | | | | | | |
| **Comments** | |  | | | | | | | |
| **Action Required** | |  | | | | | | | |
| **CTC/CTA comment** | |  | | | | | | | |
| **SECTION** | | ***6.0 Governance*** | | | | | | | |
| **ITEM** | | Site confirmation of Capability and Capacity   * 1. **Regulatory Checklists**   2. **Local Information Pack**   3. **Correspondence**   4. **Superseded Documents** | | | | | | | |
| **Comments** | |  | | | | | | | |
| **Action Required** | |  | | | | | | | |
| **CTC/CTA comment** | |  | | | | | | | |
| **SECTION** | | ***7.0 Data Management*** | | | | | | | |
| **ITEM** | | **7.1 Blank case report forms (CRFs)**  **7.2 Completed CRFs + data collection instruments**  **7.3 Data amendment forms**  **7.4 Data queries**  **7.5 Correspondence**  **7.6 Superseded Documents** | | | | | | | |
| **Comments** | |  | | | | | | | |
| **Action Required** | |  | | | | | | | |
| **CTC/CTA comment** | |  | | | | | | | |
| **SECTION** | | ***8.0 Monitoring*** | | | | | | | |
| **ITEM** | | Site Visit Log *(Held in the paper file)*  Close out report  **8.1. Monitoring Reports**  **8.2. Audit Reports**  **8.3. Remote Monitoring Documents**  **8.4. Correspondence**  **8.5 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  Instructions for randomisation, unblinding and code breaking  **9.1. RSI (Reference Safety Information)**  **9.2. Correspondence**  **9.3. Superseded Documents** | | | | | | | |
| **Comments** | |  | | | | | | | |
| **Action required** | |  | | | | | | | |
| **CTC/CTA comment** | |  | | | | | | | |
| **SECTION** | | ***10.0 Meetings*** | | | | | | | |
| **ITEM** | | **10.1. Team meetings**  **10.2. SIV Documentation**  **10.3. Correspondence**  **10.4 Superseded Documents** | | | | | | | |
| **Comments** | |  | | | | | | | |
| **Action required** | |  | | | | | | | |
| **CTC/CTA comment** | |  | | | | | | | |
| **SECTION** | | ***11.0 Laboratory*** | | | | | | | |
| **ITEM** | | **11.1 Laboratory Manual/Instructions**  **11.2 Sample Collection Worksheets**  **11.3 Sample Labels**  **11.4 Sample Storage Log**  **11.5 Sample Shipment/Receipt Tracking**  **11.6 Storage Condition Monitoring**  **11.7 Sample Destruction and/or use for future research**  **11.8 Local Certificates and Accreditation**  **11.9 Lab Reference Ranges**  **11.10 Correspondence**  **11.11 Superseded Documents** | | | | | | | |
| **Comments** | |  | | | | | | | |
| **Action Required** | |  | | | | | | | |
| **CTC/CTA Comment** | |  | | | | | | | |
| **SECTION** | | ***12.0 Device*** | | | | | | | |
| **ITEM** | | **12.1 Certificates**  **12.2 Service/PAT Testing Log**  **12.3 Device Manual/Instructions**  **12.4 Delivery/Return of Devices Log**  **12.5 Correspondence**  **12.6 Superseded Documents** | | | | | | | |
| **Comments** | |  | | | | | | | |
| **Action Required** | |  | | | | | | | |
| **CTC/CTA comment** | |  | | | | | | | |
| **SECTION** | | ***13.0 COVID-19 Pandemic*** | | | | | | | |
| **ITEM** | | **13.1 COVID-19 Impact Documents**  **13.2 Correspondence**  **13.3 Superseded Documents** | | | | | | | |
| **Comments** | |  | | | | | | | |
| **Action Required** | |  | | | | | | | |
| **CTC/CTA comment** | |  | | | | | | | |
| **EQUIPMENT** | | | | | | | | | |
| **Item(s)** | | | **Quantity** | | **Serial Number(s)** | | **Comments** | | |
|  | | |  | |  | |  | | |
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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: