|  |
| --- |
| **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 **Superseded Documents**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 **Superseded Documents**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*(Held in the paper file)***3.2 Signed Informed consent forms** *(Held in the paper file)***3.3 Correspondence****3.4 Superseded Documents** |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 **Superseded Documents**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 **Superseded Documents**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 updatesInstructions 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: