|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PHARMACY MONITORING TEMPLATE** | | | | |
| **P0 No.** |  | | **Study Title:** |  |
| **Investigator** |  | | **Monitor** |  |
| **Site Name** |  | | **Site Number** |  |
| **Date of Visit** |  | | **Site Staff**  **Present** |  |
| ***Sponsor/Investigator site file documentation*** | | | | |
| **SECTION** | | 1. ***STUDY INFORMATION*** | | |
| **ITEM** | | * 1. Copy of protocol and amendments – current version   2. Study team contact list   3. Investigator brochure/ SmPC as applicable – current version   4. Copy of study risk assessment   5. Copy of ethics approval letter   6. Copy of CTA approval   7. Copy of Trust R&D approval letter   8. Clinical Trials Agreement   9. Copy of pharmacy review and Green light approval | | |
| **Comments** | |  | | |
| **Action Required** | |  | | |
| **CTC/CTA comment** | |  | | |
| **SECTION** | | 1. ***LOGS*** | | |
| **ITEM** | | 2.1 Pharmacy Training Logs  2.2 Delegation of duties log   * 1. Sample signatures of approval pharmacy personnel | | |
| **Comments** | |  | | |
| **Action Required** | |  | | |
| **CTC/CTA comment** | |  | | |
| **SECTION** | | ***3.0 INVESTIGATIONAL PRODUCT*** | | |
| **ITEM** | | 3.1 Summary of drug arrangements  3.2 Certificate of analysis  3.3 IMPD (If applicable)  3.4 Material safety data sheet  3.5 QP certification of release for each IMP batch  3.6 Instruments for handling /Dispensing IMP including administration  3.7 Samples of study medication packaging and labelling  3.8 Patient information leaflet/consent form (blank copy)  3.9 Copy of patient alert card  3.10 Example of prescription (if applicable)  3.11 IMP storage authorisation form  3.12 Copy of code break procedure/local  3.13 Code break forms and tests   * **Guidelines for code break**  1. Are instructions for emergency code breaking available? | | |
| **Comments** | |  | | |
| **Action required** | |  | | |
| **CTC/CTA comments** | |  | | |
| **SECTION** | | ***4.0 INVESTIGATIONAL PRODUCT ACCOUNTABILITY*** | | |
| **ITEM** | | 4.1 Patient identification record  4.2 Batch reports (for post QP assembly and/or relabelling)  4.3 Study prescriptions  4.4 Study medication dispensing/accountability records  4.5 Master accountability logs   * **Accountability Logs**  1. Is the master drug accountability log maintained by the research team correct? 2. If applicable, has the patient specific drug accountability logs been completed correctly 3. Does the stock held match the documented inventory/ accountability log   4.6 Ordering and shipping records  4.7 IMP acknowledgement of receipt   * **IMP delivery**  1. Was the IMP delivered to the sponsor under the specific conditions? 2. If not, has this been reported?   4.8 Records of study medication returned to sponsor   * **Patient returns**  1. Do patient returns need to be transferred to Pharmacy?   4.9 Drug recalls  4.10 Drug destruction manual –  4.11 Records of study medication destruction at site has all drug destruction taken place after appropriate approvals have been given  4.12 Temperature monitoring records   * **Temperature Monitoring (if applicable)**  1. Has the temperature been monitored by the research team/delegated team at a frequency agreed in the study specific SOP 2. Have any manual entries been missed (excluding weekends and bank holidays) 3. Have there been any temperature excursions? If so, were they reported and was the IMP quarantined? 4. Is the temperature monitoring device working and within its calibration date?   4.13 Temperature monitoring and deviation records  4.14 Calibration certificates  4.15 Quarantine records   * **Storage**  1. Are the IMP’s in the agreed, secure storage location, and clearly marked as for the clinical trial?  * **Expiry date check**  1. Are all the investigational Medicinal Products within a suitable expiry date | | |
| **Comments** | |  | | |
| **Action required** | |  | | |
| **CTC/CTA comments** | |  | | |
| **SECTION** | | ***5.0 IVRS/IXRS*** | | |
| **ITEM** | | 5.1 User manual  5.2 IVRS/IXRS confirmations | | |
| **Comments** | |  | | |
| **Action required** | |  | | |
| **CTC/CTA comments** | |  | | |
| **SECTION** | | ***6.0 FILE NOTES*** | | |
| **ITEM** | | 6.1 Pharmacy file notes | | |
| **Comments** | |  | | |
| **Action Required** | |  | | |
| **CTC/CTA comments** | |  | | |
| **SECTION** | | ***7.0 CORRESPONDENCE*** | | |
| **ITEM** | | 7.1 Meetings  7.2 Correspondence | | |
| **Comments** | |  | | |
| **Action Required** | |  | | |
| **CTC/CTA comments** | |  | | |
| **SECTION** | | ***8.0 PHARMACY MONITORING*** | | |
| **ITEM** | | 8.1 Monitoring Visit log  8.2 Monitoring reports | | |
| **Comments** | |  | | |
| **Action Required** | |  | | |
| **CTC/CTA comments** | |  | | |
| **SECTION** | | ***9.0 THIRD PARTY VENDORS*** | | |
| **ITEM** | | 9.1 Vendor information – Licenses, SOP’s, Quotes  9.2 Technical agreement  9.3 Meetings and Correspondence  9.4 Client approval documents | | |
| **Comments** | |  | | |
| **Action Required** | |  | | |
| **CTC/CTA comments** | |  | | |

|  |
| --- |
| **SUMMARY OF ACTION POINTS – please state who is to action and by when** |
|  |

Monitor’s Signature Date

Principal Investigator’s Signature Date

Study Pharmacist signature …………………………………... Date ………………………

**Used IMP summary:** *amend for study design*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Kit or bottle? No:** | **Reasons for Breaking code** | **Broken by**  **(INITIALS)** | **Date** | **Time** | **Treatment** | **Number of tablets remaining** | **Bottle signed by** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |