**Joint Research Management Office**

***Pharmacy Visit* *Monitoring Form***

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| 1. **GENERAL INFORMATION** | |
| **Study Title:** | **Sponsor:** |
| **Study IRAS number:** | **CI:** |
| Site: | Site number: |
| PI: | Date of visit: |
| Study coordinator: | Type of visit (i.e. visit no., COV): |
| Names of all study personnel met during this visit: |  |
| Locations and departments visited: | Name of the monitor: |
| Next scheduled visit date (refer to study monitoring plan): | Risk level of this study (as defined by the JRMO): |
| **Summary of the Visit:** | |
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| **2. PREVIOUS VISIT FINDINGS STATUS** | | | | | | |
| **Have all previous visit findings been resolved?**  **Yes  No  If NO detail outstanding findings below:** | | | | | | |
|  | **Finding type (please see key for details)** | **Summary of findings** | **Corrective action and person carrying out this action** | **Severity (Critical, Major, Other)** | **Proposed timeline to resolve** | **Date action completed** |
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| **SAFETY FIRST! PLEASE BE AWARE THAT GLOVES MUST BE WORN AT ALL TIMES WHEN HANDLING DRUGS ESPECIALLY CYTOTOXIC DRUGS. ASK THE PHARMACIST FOR A PAIR** | | | | | | | | | | | | |
| 1. **DOCUMENTATION** | | | | | | **Yes** | | **No** | **N/A** | **Comment** | | |
| 3.1 Is the pharmacy file presented in an acceptable condition? | | | | | |  | |  |  |  | | |
| 3.2 Are all essential documents (protocol and, IB’s, SmPC’s etc.) up-to-date and located in the pharmacy file? Ensure that these reflect any recent amendments | | | | | |  | |  |  | ***Protocol***   |  |  |  |  | | --- | --- | --- | --- | | Version | Date | Present | Marked superseded? | |  |  |  |  | |  |  |  |  |   ***Investigator Brochure/ SMPC***   |  |  |  |  | | --- | --- | --- | --- | | Version | Date | Present | Marked superseded? | |  |  |  |  | |  |  |  |  |   ***Pharmacy manual***   |  |  |  |  | | --- | --- | --- | --- | | Version | Date | Present | Marked superseded? | |  |  |  |  | |  |  |  |  |   *Please add tables for other documentation present i.e. IMP dossier, contact list etc.* | | |
| 3.3 Are all regulatory approvals (Ethics, MHRA and local approvals) located in the pharmacy file? | | | | | |  | |  |  | ***Ethics***   |  |  |  | | --- | --- | --- | |  | Date | Present | | Initial |  |  | | A#1 |  |  | | A#2 |  |  |   ***MHRA***   |  |  |  | | --- | --- | --- | |  | Date | Present | | Initial |  |  | | A#1 |  |  | | A#2 |  |  |   **Local approvals (including C and C and pharmacy)**   |  |  |  | | --- | --- | --- | |  | Date | Present | | Initial |  |  | | A#1 |  |  | | A#2 |  |  | | | |
| * 1. QP Declaration concerning IMPs manufactured in Third Countries   *(for studies where IMP is sourced outside of the EU only)* | | | | | |  | |  |  |  | | |
| 3.5 TSE Statements *(for novel IMPs (i.e. unlicensed)* | | | | | |  | |  |  |  | | |
| 3.6 Is a copy of the Clinical Trial Site Agreement available in the pharmacy file? | | | | | |  | |  |  |  | | |
| 3.7 Is a separate financial agreement in use for this study? Is this available in the pharmacy file? | | | | | |  | |  |  |  | | |
| * 1. Records of invoices/payments *(provide details of outstanding invoices)* | | | | | |  | |  |  | *Are all payments up-to-date?*  *Any outstanding invoices?* | | |
| 3.9 For studies where IMP is sourced outside of the EU, ensure that a copy of the MIA (IMP) import licence of the Third party responsible for import is available in the pharmacy file. | | | | | |  | |  |  |  | | |
| 3.10 Have site specific dispensing procedures been created for this study? | | | | | |  | |  |  | *(confirm that these are acceptable and in line with the protocol and pharmacy manual)* | | |
| 3.11 Template study specific prescription present | | | | | |  | |  |  |  | | |
| 3.12 Have any file notes been created pertaining to events involving IMP(s)? | | | | | |  | |  |  | *(provide details of any file notes created pertaining to IMP-related events)* | | |
| 3.14 Is the ***Delegation*** log up to date and complete? | | | | | |  | |  |  |  | | |
| 3.15 Are CV’s, GCP certificates, training records up to date and available for all CT pharmacy staff? | | | | | |  | |  |  | |  |  |  | | --- | --- | --- | | Name | CV date | GCP certificate date | |  |  |  | |  |  |  | |  |  |  | | | |
| 3.16 Is all documentation legible, with corrections completed correctly? | | | | | |  | |  |  |  | | |
| 1. **IMP MANAGEMENT** | | | | | | **Yes** | | **No** | **N/A** | **Comments** | | |
| **General** | | | | | | | | | | | | |
| 4.1 Are there dedicated clinical trial staff to undertake IMP management? | | | | | |  | |  |  |  | | |
| 4.2 For IMP(s) sourced from commercial stock – confirm that the IMP(s) be labelled as clinical trials supply and in line with Annex 13? | | | | | |  | |  |  |  | | |
| **Facilities** | | | | | | | | | | | | |
| 4.3 Are calibrated thermometers used for temperature monitoring of IMP(s)? | | | | | |  | |  |  | **Calibration date:**  **Next calibration due date:** | | |
| 4.4 If electronic prescribing systems are used, confirm that the system has been validated? Confirm the process for entering new studies onto the system? | | | | | |  | |  |  |  | | |
| 4.5 Provide details of the process for entering new studies onto the electronic prescribing system. | | | | | |  | |  |  |  | | |
| 4.6 Are IMP(s) located in a segregated area, designated for clinical trials? *(This should be separate from normal stock)* | | | | | |  | |  |  |  | | |
| 4.7 Is there an identified Quarantine area for study medication? | | | | | |  | |  |  | *Location of quarantine area:* | | |
| **Other** | | | | | | | | | | | | |
| 4.9 Have accountability logs been maintained correctly? | | | | | |  | |  |  |  | | |
| 4.10 Verify that the amount of IMP on site matches the delivery notes and accountability logs | | | | | |  | |  |  | **Amount of IMP stated on accountability log (for each batch):**  **Physical count (for each batch):** | | |
| 4.11 Review the temperature monitoring records for the appropriate time period | | | | | |  | |  |  | **Time period:**  From …/…/... to …/…/... | | |
| 4.12 Have any temperature excursions occurred requiring further investigation? *(Include excursions that have occurred during transit)* | | | | | |  | |  |  |  | | |
| 4.13 Has destruction of any IMP been authorised by the Sponsor? Are destruction certificates located in the file? | | | | | |  | |  |  |  | | |
| 4.14 Ensure that Certificates of Analysis and QP release documents for all batches of IMP received on site are available in the file | | | | | |  | |  |  |  | | |
| 4.15 Is there sufficient IMP on site based on number of patients? | | | | | |  | |  |  |  | | |
| 4.16 Confirm the expiry date of IMP on site. Is this acceptable? | | | | | |  | |  |  | |  |  |  | | --- | --- | --- | | Batch Number | Expiry date | Within acceptable limits? | |  |  |  | |  |  |  | |  |  |  | | | |
| 4.17 Are there on-site destruction facilities available? *If yes, please ensure a copy of local destruction SOPs are include in the file* | | | | | |  | |  |  |  | | |
| **5.0 UNBLINDING** | | | | | | **Yes** | | **No** | **N/A** | **Comments** | | |
| 5.1 Are there unblinding procedures in place? *(Ensure copy of procedure is retained for study TMF)* | | | | | |  | |  |  |  | | |
| 5.2 For blinded studies, ensure that any code-breaks envelopes are present and in good condition i.e. not tampered with. | | | | | |  | |  |  |  | | |
| **6.0ARCHIVING** | | | | | | **Yes** | | **No** | **N/A** | **Comments** | | |
| 6.1 Are there archiving facilities available? | | | | | |  | |  |  |  | | |
| 1. **SOPS IN PLACE TO COVER** | | | | | | **Yes** | | **No** | **N/A** | **Comments** | | |
| 7.1 Receipt | | | | | |  | |  |  |  | | |
| 7.2 Storage | | | | | |  | |  |  |  | | |
| 7.3 Dispensing | | | | | |  | |  |  |  | | |
| 7.4 Checking | | | | | |  | |  |  |  | | |
| 7.5 IMP destruction | | | | | |  | |  |  |  | | |
| 7.6 Temperature monitoring | | | | | |  | |  |  |  | | |
| 7.7 Relabelling | | | | | |  | |  |  |  | | |
| 7.8 Study medication recall procedures | | | | | |  | |  |  |  | | |
| 7.9 Archiving | | | | | |  | |  |  | *Copy of the sites archiving procedure available?* | | |
| 7.10 General comments | | | | | | | | | | | | |
| 1. **PATIENT SPECIFIC** | | | **Yes** | **No** | | | **N/A** | | **Comments** | | | |
| 8.1 Is the recruitment log up-to-date and complete? | | |  |  | | |  | |  | | | |
| 8.2 How is pharmacy alerted to new recruits? | | |  |  | | |  | |  | | | |
| **9.0 For EACH patient entered onto the study:** | | | | | | | | | | | | |
| 9.1 Ensure that randomisation details (fax/email) are present, verifying which arm/cohort each patient has been randomised to. | | |  |  | | |  | |  | | | |
| 9.2 Identify how many dispensing episodes have occurred for each patient. | | |  |  | | |  | | **Detail as per protocol:** | | | |
| 9.3 Are all dispensing episodes correct?  Are all prescriptions and/or worksheet available for each of episodes? | | |  |  | | |  | | |  |  |  | | --- | --- | --- | | Patient Study No | Number of dispensing episodes | Prescription /worksheet present Y/N | |  |  |  | |  |  |  | |  |  |  |   **If no specify:** | | | |
| 9.4 Confirm that each prescription/worksheet matches the accountability logs and that entries have been made for each dispensing episode | | |  |  | | |  | | **If no specify:** | | | |
| 9.5 Confirm that sufficient IMP was dispensed as per prescription and protocol | | |  |  | | |  | | **If no specify:** | | | |
| 9.6 Verify and document the exact number of returns for each patient | | |  |  | | |  | |  | | | |
| 9.7 For studies where IMP is taken from commercial stock, ensure that the batch numbers and expiry dates are documented and that the source documents are filed in the pharmacy file | | |  |  | | |  | |  | | | |
| 9.8 For studies which require a specific kit number to be dispensed, verify that the correct kit number has been dispensed for each visit | | |  |  | | |  | |  | | | |
| 9.9 Ensure that original documentation to support the allocation/dispensing of medication kits for blinded studies is available in file | | |  |  | | |  | |  | | | |
| 9.10 Are there any concerns relating to study compliance? *(i.e. numerous returns which cannot be accounted for)* | | |  |  | | |  | |  | | | |
| 10. SUMMARY OF FINDINGS AND ACTIONS | | | | | | | | | | | | |
|  | **Finding type (please see key for details)** | **Summary of findings** | | | **Corrective action and person carrying out this action** | | | | | **Severity (Critical, Major, Other)** | **Proposed timeline to resolve** | **Date action completed** |
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**Key for Findings type:**

1. Essential documents
   1. Study
   2. Approvals
2. Vendors / contracts / subcontractor/ finance
3. Informed consent procedures
4. Inclusion and exclusion criteria
5. IMP and non-IMP
6. Training + Staffing
7. Deviation Study procedures
8. Pharmacovigilance
9. Randomisation and cohort allocation / un-blinding
10. Data Management (Source data + CRF)
11. Study equipment
12. Computer Systems
13. Deviations to GCP / Regulations

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| --- | --- | --- | --- |
| 11. SIGNATURES AND REVIEW | | | |
| Completed by: | | | |
| Study Monitor | **Name:**  **Email:** | Date: | Signature |
| Reviewed by | | | |
| Research Governance and GCP Manager | **Name:**  **Email:** | Date | Signature |