**Joint Research Management Office**

***Investigator Site File (ISF) Monitoring Form***

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| 1. **GENERAL INFORMATION** | |
| **Study Title:** | **Sponsor:** |
| **Study IRAS number:** | **Chief Investigator (CI):** |
| Site: | Site number: |
| PI: | Date of visit: |
| Study coordinator: | Type of visit (i.e., visit no., Close Out Visit (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:** | |
| ***Please ensure a comment is inserted regarding meeting with PI.*** | |

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| **2. STUDY ACCRUAL AND STATUS** | | | |
| **ACCRUAL** | | | |
| **Study subject status** | **Number** | **Comments** | |
| Screened |  | *Total number of participants approached or assessed for eligibility* | |
| Consented |  | *Total number of participants who have signed a consent form.* | |
| Enrolled |  | *Total number of participants who have completed all eligibility assessments and have been entered into the study.* | |
| On-going |  | *Number of participants currently taking part in the study (including those in follow-up).* | |
| Completed |  | *Number of participants who have completed all study visits and activities per protocol.* | |
| Withdrawn |  | *Number of participants who withdrew or were withdrawn from the study before reaching the end of the study per protocol.* | |
| **STATUS** | | | |
|  | | **Yes/No** | **Comments and summary of discussion where applicable** |
|  | PI meet? | Yes No | *Insert detail- face to face etc.* |
| **Does the PI have any concerns about the study?** | |  |  |
| 1 | Recruitment rate | Yes No |  |
| 2 | Resources | Yes No |  |
| 3 | Number of staff members | Yes No |  |
| 4 | Data collection | Yes No |  |
| 5 | Equipment | Yes No |  |
| 6 | Sourcing of the IMP | Yes No |  |
| 7 | Storage of the IMP | Yes No |  |
| 8 | Dispensing of the IMP | Yes No |  |
| 9 | Accountability of the IMP | Yes No |  |
| 10 | New vendor/subcontracts | Yes No |  |

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| **3. 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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| **4. ESSENTIAL DOCUMENTATION** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Is the ISF/ up to date and filed in appropriate order?** | **YES/NO** *(Please insert comments)* | | | | | | |
| **Current documents** | **Version in use** | **Sponsor approval (Date)** | **MHRA approval (Date)** | **REC approval (Date)** | **Present in the ISF?** | **Comments** |
| Protocol |  |  |  |  | Yes  No |  |
| PIS |  |  |  |  | Yes  No |  |
| ICF |  |  |  |  | Yes  No |  |
| GP letter |  |  |  |  | Yes  No |  |
| Contact list |  |  |  |  | Yes  No |  |
| Other comments: | | | | | | | | |

| **Superseded documents**  *(Insert multiple lines)* | **Version and date** | **Present in the ISF?** | **Marked as superseded** |
| --- | --- | --- | --- |
| Protocol |  | Yes  No | Yes  No  N/A |
| Patient information sheet |  | Yes  No | Yes  No  N/A |
| Informed consent forms |  | Yes  No | Yes  No  N/A |
| GP letter |  | Yes  No | Yes  No  N/A |
| Please add rows for each REC approved docs (questionnaires, posters, adverts etc.) |  | Yes  No | Yes  No  N/A |

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| **Documents Present in Study Files** | | | | | |
| **R&D APPROVAL** | **Yes** | | **No** | **N/A** | **Comments** |
| IRAS Form |  | |  |  |  |
| Sponsorship with conditions |  | |  |  | *It is noted that documents names change over time– please specify as needed* |
| Confirmation of sponsorship |  | |  |  | *It is noted that documents names change over time– please specify as needed* |
| ARSAC licence |  | |  |  |  |
| Pharmacy Approval |  | |  |  |  |
| Imaging approval |  | |  |  |  |
| Capability and capacity |  | |  |  | *It is noted that documents names change over time– please specify as needed and Insert date granted* |
| **ETHICS APPROVAL** | **Yes** | | **No** | **N/A** | **Comments** |
| Complete Initial Ethics submission |  | |  |  | *Please list documents present ( including signed application)* |
| Ethics approval letter/s |  | |  |  | *Please list documents present* |
| Any Interim correspondence and re-submissions |  | |  |  | *Please list documents present* |
| Evidence conditions of approval met |  | |  |  | *Please list documents present* |
| **MHRA APPROVAL** | **Yes** | | **No** | **N/A** | **Comments** |
| Complete Initial MHRA submission |  | |  |  | *Please list documents present (including signed CTA application form)* |
| MHRA approval letter |  | |  |  | *Please list documents present* |
| Interim correspondence and re-submissions |  | |  |  | *Please list documents present* |
| Evidence conditions of approval met |  | |  |  | *Please list documents present* |
| **HRA APPROVAL** | **Yes** | | **No** | **N/A** | **Comments** |
| HRA approval letter |  | |  |  | *Please list documents present* |
| Interim correspondence and re-submissions |  | |  |  | *Please list documents present* |
| Evidence conditions of approval met |  | |  |  | *Please list documents present* |
| **AMENDMENTS (Since Site Opened)** | **Yes** | | **No** | **N/A** | **Comments** |
| Amendment log present |  | |  |  | *Was the log up to date?* |
| Summary of all amendments (substantial and non-substantial) |  | |  |  | Amendment type, number and date:  Peer review/ statistical review (where applicable):  HRA approval:  REC submission letter:  REC approval:  MHRA submission letter:  MHRA approval:  List approved documents present in ISF |
| Has the study been ‘temporarily halted’ |  | |  | *If yes indicate here which amendment reflects this* | |
| Have there been any Urgent Safety Measures? |  | |  |  | |
| Expedited safety information received and filed |  | |  |  | |
|  |  | |  |  | |
| **CONTRACTS AND FUNDING** | **Yes** | | **No** | **N/A** | **Comments** |
| Model Clinical Trial Agreements |  | |  |  | *Insert date, (sponsor to site)* |
| Other |  | |  |  |  |
| **DATA MANAGEMENT** | **Yes** | | **No** | **N/A** | **Comments** |
| Blank copy of all CRF versions |  | |  |  |  |
| Source data list present |  | |  |  |  |
| Were CRFs up to date? |  | |  |  |  |
| Does the CRF capture dose given, dose calculation and dose escalation/reduction as per protocol? |  | |  |  |  |
| Does the CRF capture patients’ follow up as per protocol? |  | |  |  |  |
| Have all corrections on the CRFs been made in compliance with GCP |  | |  |  |  |
| Are all the staff who are completing the CRF delegated to do so? |  | |  |  |  |
| Are all CRFs pseudo anonymised? |  | |  |  |  |
| Were CRFs completed in a timely fashion? |  | |  |  |  |
| Has the PI signed off all completed CRFs |  | |  |  | If partially completed, please specify |
| **DATABASE** | **Yes** | | **No** | **N/A** | **Comments** |
| Training on database |  | |  |  | *eCRF specific training required.* |
| **PATIENT LOGS AND CONSENT FORMS** | **Yes** | | **No** | **N/A** | **Comments** |
| Screening log completed and up to date |  | |  |  |  |
| Recruitment log completed and up to date |  | |  |  |  |
| **STUDY PERSONNEL** | | | | | |
| Site delegation log |  | |  |  |  |
| Training log present |  | |  |  |  |
| **All documentation present, and correct? Yes**  **No** for details see below | | | | | |
| |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **Name** | **On Delegation log?** | **Role within the study** | **CV present and signed**  *(Please insert date)* | **GCP certificate**  *(Please insert date)* | **Study specific Training**  *(Including protocol and SOPs training)* | **Delegated appropriate duties? Y/N** | |  | Yes  No |  |  |  |  |  | |  | Yes  No |  |  |  |  |  | |  | Yes  No |  |  |  |  |  | | | | | | |
| **INVESTIGATIONAL MEDICINAL PRODUCT** | **Yes** | | **No** | **N/A** | **Comments** |
| Pharmacy used (provide Location and address) |  | | | | |
| Specify IB or SmPC versions for each IMP | *Including expedited Safety information.* | | | | |
| Have the IB or SmPC been updated appropriately? |  | |  | *Have all versions been distribution to site?* | |
| IMP dossier |  | |  |  |  |
| Study specific pharmacy SOP(s) |  | |  |  |  |
| Pharmacy manual |  | |  |  |  |
| Sample label attached to IMP(s) |  | |  |  |  |
| Prescription template |  | |  |  |  |
| **LABORATORIES** | **Yes** | **No** | | **N/A** | **Comments** |
| Name, address and role of each lab used | *Please insert what each lab is doing, repeat below for each lab in use.* | | | | |
| UKAS accreditation certificate and letters |  |  | |  | *Include date issued (NB. Updated yearly )* |
| CV for the Head of each lab |  |  | |  |  |
| All labs normal ranges present |  | |  |  |  |
| Record of retained body fluids/tissue samples |  | |  |  |  |
| Name and address of other medical/technical departments used |  | |  |  |  |
| Are all labs listed above known to JRMO? |  | |  |  |  |
| **OTHER DEPARTMENTS USED** | **Yes** | | **No** | **N/A** | **Comments** |
| Radiology (Imaging, X ray etc.) |  | |  |  |  |
| Records of transfer test for scans |  | |  |  |  |
| Other departments |  | |  |  |  |
| **STANDARD OPERATING PROCEDURES** | | | | | |
| SOP log |  | |  |  |  |
| **Name of SOP** | **Version** | | **Review date** | | **Comment** |
|  |  | |  | |  |
|  |  | |  | |  |
| **FILE NOTES** | **Yes** | | **No** | **N/A** | **Comments** |
| File note log present? |  | |  |  |  |
| File notes created |  | |  |  | *List any created since last visit* |
| **MEDICAL EQUIPMENT AND DEVICES** | **Yes** | | **No** | **N/A** | **Comments** |
| All equipment listed in Site File, including storage location and custodian? |  | |  |  |  |
| Is the equipment maintenance log up to date (all kit maintained annually unless specified by clinical physics) |  | |  |  |  |
| Serial numbers of all devices and equipment listed in log? |  | |  |  |  |
| Was equipment calibrated at start of study? |  | |  |  |  |
| Equipment manual/instructions in place? |  | |  |  |  |
| Evidence of training on equipment in training log? |  | |  |  |  |
| **CORRESPONDENCE** | **Yes** | | **No** | **N/A** | **Comments** |
| Is there any correspondence present? |  | |  | *Check for key decision-making key activities and CI involvement and oversight* | |
| **CLOSE OUT DOCUMENTATION** | **Yes** | | **No** | **N/A** | **Comments** |
| Planned date of LPLV |  | |  |  |  |
| Has the study been extended? |  | |  |  | *If yes, please specify and confirm Local R&D informed* |
| Are all samples shipped to sponsor as per protocol? |  | |  |  | *Protocol will state what should happen to tissue at the end of the study* |
| REC End of study notification and acknowledgement |  | |  |  | *Dates documents sent, received and acknowledged* |
| MHRA End of Study notification and acknowledgement |  | |  |  | *Date sent to MHRA, Ethics and R&D* |
| Local R&D informed |  | |  |  | *Email evidence* |
| Final study report |  | |  |  |  |

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| **5. SOURCE DATA VERIFICATION (SDV) (AS PER MONITORING PLAN)** | |
| SDV was performed on: (List CRFs reviewed i.e., GP letters have been sent, Quality of life questionnaires, patients diary card) | |
| Participant # | CRF section |
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| I confirm that apart from those data points listed below, a full reviewed of data points was performed and were found to be correct, accurate and source was identified. | |

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| **PARTICIPANT MEDICAL NOTES/ SOURCE DATA** | | |
| Please List Source data ( one row per source): | e.g. Paper medical records, electronic system- millennium, E-MR print outs, PACS etc.) | |
| Name | Type | If electronic – has this been validated? |
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| CRFs SDV performed on  (Visit no.) | Query no. | Comments | Action | | Date query resolved/ comments |
| --- | --- | --- | --- | --- | --- |
| **Patient no.** | | | | | |
|  | 1 |  |  | |  |
|  | 2 |  |  | |  |
|  | 3 |  |  | |  |
| For sections reviewed: | | | |  | *Comments:* |
| Assessments and tests completed in line with the protocol? | | | | Yes  No |  |
| Does the frequency (and dose) of prescription match what is stated in the protocol? | | | | Yes  No |  |
|  | | | Yes  No | |  |
| Are all **AEs** accounted for and recorded in the CRF? | | | Yes  No | |  |
| Have all AEs been followed up and closed? | | | Yes  No | |  |
| Are all **SAEs** accounted for and recorded in the CRF? | | | Yes  No | |  |
| Have all SAEs been followed up and closed? | | | Yes  No | |  |
| Have all SUSARs been recorded in CRF and reported to the sponsor? | | | Yes  No | |  |
|  | | |  | |  |
| **Patient no.** | | | | | |
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| For sections reviewed: | | | |  | *Comments:* |
| Assessments and tests completed in line with the protocol? | | | | Yes  No |  |
| Does the frequency (and dose) of prescription match what is stated in the protocol? | | | | Yes  No |  |
| Are all **AEs** accounted for and recorded in the CRF? | | | Yes  No | |  |
| Have all AEs been followed up and closed? | | | Yes  No | |  |
| Are all **SAEs** accounted for and recorded in the CRF? | | | Yes  No | |  |
| Have all SAEs been followed up and closed? | | | Yes  No | |  |
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| **Patient no.** | | | | | |
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| For sections reviewed: | | | |  | *Comments:* |
| Assessments and tests completed in line with the protocol? | | | | Yes  No |  |
| Does the frequency (and dose) of prescription match what is stated in the protocol? | | | | Yes  No |  |
| Are all **AEs** accounted for and recorded in the CRF? | | | Yes  No | |  |
| Have all AEs been followed up and closed? | | | Yes  No | |  |
| Are all **SAEs** accounted for and recorded in the CRF? | | | Yes  No | |  |
| Have all SAEs been followed up and closed? | | | Yes  No | |  |
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| **6. INFORMED CONSENT/ ELIGIBILITY CRITERIA** | | | | | | | | | | |
| Consent form present for all participants on Screening and enrolment log? Yes  No | | | | | | | | | | |
| Pt ID | PIS v | ICF v | Date signed by | | Name of researcher receiving consent | Researcher on delegation log? | Boxes initialled? | Satisfies inclusion / exclusion | Status (if withdrawn, why) | Comments |
| Participant | Researcher |
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| Does the date on the first informed consent form predate any study related activities? | | | | Yes | No | N/A | *Insert date on the first consent* | **Comments** | | |

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| **7. DEVIATIONS** | **Yes** | **No** | **N/A** | **Comments** |
| Protocol deviation log |  |  |  |  |
| Have any deviations been logged? |  |  |  |  |
| Were any of these potential serious breaches? |  |  |  | *Reconcile with JRMO records* |
| Have any breaches of patient confidentiality occurred? |  |  |  |  |
| Related correspondence |  |  |  |  |

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| **8. PHARMACOVIGILANCE** | **Yes** | **No** | **N/A** | **Comments** |
| Does the SAE log match the records from the sponsor? |  |  |  |  |
| Were all SAE forms signed by PI/co-investigators? |  |  |  |  |
| Drug recalls or correspondence related to safety |  |  |  |  |
| All pregnancies reported, accounted and followed up in the CRF |  |  |  |  |

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| 9. MONITORING AND AUDIT | | | | |
| **This visit** | **Yes** | **No** | **N/A** | **Comment** |
| Any resistance or delay in scheduling the monitoring visit? |  |  |  | |
| Was all documentation requested made available? (Patient notes, scans etc) |  |  |  | |
| Did study staff have adequate time for the monitoring visit? |  |  |  | |
| Was a suitable area set aside for monitoring? |  |  |  | |
| Was there enough time at site to perform required monitoring? |  |  | *If not explain why? Will an extra day be added?* | |
| Was the monitoring log signed? |  |  |  |  |
| Previous monitoring reports filed? |  |  |  |  |
| Previous monitoring visit findings resolution and correspondence filed? |  |  |  |  |
| Study monitoring plan present |  |  |  | *Please list all versions* |
| Study recruitment centre on site monitoring tool |  |  |  |  |
| Has this study been audited? |  |  |  |  |
| Has this study been inspected? |  |  |  |  |

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| 10. SUMMARY OF FINDINGS AND ACTIONS | | | | | | |
| **Finding Number** | **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 | | | |
| *Insert role ( default is RG and GCP manager)* | **Name:**  **Email:** | Date | Signature |