**Joint Research Management Office**

***Combined TMF review and ISF Monitoring - for Single-Centre Device Studies***

|  |  |
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| 1. **GENERAL INFORMATION** | |
| **Study Title:** | **Sponsor:** |
| **Study IRAS number:** | **CI:** |
| Site: | Site number: |
| CI and PI: | Date of visit: |
| Study coordinator: | Date visit due per monitoring plan: |
| Names of all study personnel met during this visit: | Type of visit (i.e. visit no., COV): |
| 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 eligibity* | | | |
| 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| Withdrawn |  | *Number of participants who withdrew or were withdrawn from the study before reaching the end of the study per protocol.* | | | |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 met?** | | Yes  No | |  | |
| **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 Device | Yes  No | |  | |
| 7 | Storage of the Device | Yes  No | |  | |
| 8 | Dispensing of the Device | Yes  No | |  | |
| 9 | Accountability of the Device | 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 TMF/ up to date and filed in appropriate order?** | **YES/NO** *(Please insert comments)* | | | | | | |
| **Current documents** | **Version in use** | **Sponsor approval** | | **MHRA approval** | | **REC approval** | |
| **Date approved** | **Present in the TMF/ISF?** | **Date approved** | **Present in the TMF/ISF?** | **Date approved** | **Present in the TMF/ISF?** |
| CIP (Signed and dated by the CI and PI) |  |  | Yes  No |  | Yes  No |  | Yes  No |
| Patient information sheet |  |  | Yes  No |  | Yes  No |  | Yes  No |
| Informed consent forms |  |  | Yes  No |  | Yes  No |  | Yes  No |
| GP letter |  |  | Yes  No |  | Yes  No |  | Yes  No |
| Contact list |  |  | Yes  No |  | Yes  No |  | Yes  No |
| Please add rows for each REC approved docs (questionnaires, posters, adverts etc.) |  |  | Yes  No |  | Yes  No |  | Yes  No |
| Other comments: | | | | | | | |

| **Superseded documents**  *(Insert multiple lines)* | **Version and date** | **Marked as superseded** |
| --- | --- | --- |
| CIP (Signed and dated by the CI and PI) |  | Yes  No |
| Patient information sheet |  | Yes  No |
| Informed consent forms |  | Yes  No |
| GP letter |  | Yes  No |
| Contact list |  | Yes  No |
| Please add rows for each REC approved docs (questionnaires, posters, adverts etc.) |  | Yes  No |

| **Document Present in Study Records** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **SPONSORSHIP APPROVAL** | | **Yes** | **No** | **N/A** | **Comments** | |
| Initial Submission to JRMO email and submission |  | |  |  | *State if evidence of this is present – Do not list documents* | |
| Sponsorship with conditions |  | |  |  | *It is noted that documents names change over time– please specify as needed* | |
| Permission to activate sites letter/email (or equivalent) |  | |  |  |  | |
| ARSAC licence |  | |  |  |  | |
| Risk assessments |  | |  |  |  | |
| Clinical Physics approval |  | |  |  |  | |
| Correspondence relating to JRMO set up phase |  | |  |  |  | |
| Other relevant approvals (please specify) |  | |  |  |  | |
| Permission to activate sites (final sponsor approval) |  | |  |  |  | |
| Capacity and Capability (C&C) |  | |  |  |  | |
| Laboratory approval |  | |  |  |  | |
| Imaging approval |  | |  |  | *Consider if approval needed if study uses imaging ( X-ray, MRI, CT, angiograms, ultrasound etc), outside of standard care* | |
| **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 presents (Including signed CTA application form)* | |
| MHRA no objection letter (inc. conditions requested in approval letter) | |  |  |  | *Include conditions requested by the MHRA and who it has been delegated to, i.e device manufacturer* | |
| Interim correspondence and re-submissions | |  |  |  | *Please ist documents present, this is likely to take email format, to Manufacture ensure you have all responses from the MHRA and replies and JRMo approvals* | |
| 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* | |
| **OTHER APPROVALS** | | **Yes** | **No** | **N/A** | **Comments** | |
| Emergency out of hours contact testing | |  |  |  |  | |
| Imaging transfer testing | |  |  |  |  | |
| Other | |  |  |  |  | |
| **AMENDMENTS** | | **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):*  *JRMO authorisation for submission: HRA approval:*  *REC submission letter:*  *REC acknowledgement:*  *REC approval:*  *MHRA submission letter:*  *MHRA acknowledgement:*  *MHRA approval:*  *JRMO acknowledgement:*  *List approved documents present in ISF* | |
| Has the study been ‘temporarily halted’ | |  |  | *If Yes indicate here which amendments reflects this* | | |
| **CONTRACTS AND FUNDING** | **Yes** | | **No** | **N/A** | **Comments** | |
|  |  | |  |  |  | |
| Letters of insurance |  | |  |  | *Ensure evidence is present of documents to cover the study to set up to present day.* | |
| Funding award letter |  | |  |  | *Specify name of funder and duration* | |
| Manufacture provider agreement |  | |  |  | *Specify name of manufacture and duration* | |
| Investigational Device Provider agreement |  | |  |  | *Specify name and duration Specify if loan ,gift or single use* | |
| Technical agreement |  | |  |  | *Specify name of parties and duration* | |
| Laboratory agreement |  | |  |  |  | |
| Were any non investigational devices provided as a gift or a loan? |  | |  |  | *e.g laptop etc* | |
| If yes, Loan/Gift agreement in place for devices? |  | |  |  |  | |
| Sponsor-Site Agreement (mCTA) |  | |  |  | *Insert site name and date* | |
| Any other contracts |  | |  |  |  | |
| Are all these contract saved in EDGE (Green Level)? |  | |  |  |  | |
| **DATA MANAGEMENT** | **Yes** | | **No** | **N/A** | **Comments** | |
| Is the CRF paper or electronic? | |  | | | | |
| Blank copy of all CRF versions | |  |  | *Please supply name, version number and date of the document(s)* | | |
| CI and statistician sign off | |  |  |  | *For each version as listed above* | |
| CRF Guidance | |  |  |  | *Including timelines for submission of CRFs* | |
|  | |  |  |  |  | |
| Does the CRF capture device given, prescribed usage as per protocol? | |  |  |  |  | |
| Does the CRF capture patients’ follow up as per protocol? | |  |  |  |  | |
| Are all CRFs pseudo anonymised? | |  |  |  |  | |
| Have CRFs been completed and submitted appropriately? | |  |  |  |  | |
| Have the PI signed off all completed CRFs | |  |  |  | If partially completed please specify | |
| **DATABASE** | | **Yes** | **No** | **N/A** | **Comments** | |
| What database is being used? | |  |  |  | *Please list the name of the software, the network hosting it and the person responsible for the database* | |
| What is the current version? | |  | | | | |
| Change control log present | |  |  |  | *Please confirm if this is present and being completed accordingly* | |
| Database validation documentations | |  |  |  |  | |
| Database specifications present? | |  |  |  |  | |
| Evidence of UAT performed and result? | |  |  |  |  | |
| Evidence of JRMO review and agreement? | |  |  |  | *Database security confirmed* | |
| Evidence of CI and Statistician sign off? | |  |  |  |  | |
| System is being routinely back-up (for accidental loss, disaster recovery) | |  |  |  | *How often and by whom? Is this according to the database SOP (See SOP 38d Data Management)* | |
| Documentation on who has access to database | |  |  |  |  | |
| Training on database for all users | |  |  |  |  | |
| Any other database related issues (interaction with other systems, audit studies) | |  |  |  |  | |
| **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** | | | | | | |
| **All documentation present and correct? Yes**  **No**  for details see below | | | | | | |
| |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **Name** | **On Delegation log?** | **Role within the study** | **CV**  *(please insert date)* | **ISO14155 and GCP certificate**  *(please insert date)* | **Study specific Training**  *(including protocol ,SOPs training, device training and database training)* | **Delegated appropriate duties? Y/N** | |  | Yes  No |  |  |  |  |  | |  | Yes  No |  |  |  |  |  | |  | Yes  No |  |  |  |  |  | | | | | | | |

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| **LABS** | **Yes** | | | **No** | | **N/A** | | **Comments** | |
| Name and 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 list above known to JRMO? |  | | |  | |  | |  | |
| **OTHER DEPARTMENTS USED** | **Yes** | | | **No** | | **N/A** | | **Comments** | |
| Radiology (Imaging, X ray etc.) |  | | |  | |  | | *Include address and role in study* | |
| Records of transfer test for scans |  | | |  | |  | |  | |
| Other departments |  | | |  | |  | |  | |
| **Standard operating procedures (SOPs)** | | | | | | | | | |
| SOP log |  | | |  | |  | |  | |
| **Name of SOP** | **Version** | | | **Date of expiry** | | | | **Comment** | |
|  |  | | |  | | | |  | |
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| **FILE NOTES** | **Yes** | | | **No** | | **N/A** | | **Comments** | |
| File note log present? |  | | |  | |  | |  | |
| File notes created |  | | |  | |  | | *List any created since last visit* | |
| **TRIAL COMMITTEE(S)** | | | | | | | | | |
| List all committees as per protocol |  | | | | | | | | |
| **Per committee listed above** | **Yes** | | | **No** | | **N/A** | | **Comments** | |
| Signed charter |  | | |  | |  | |  | |
| Member list |  | | |  | |  | |  | |
| CV and GCP training present for all members |  | | |  | |  | |  | |
| Conflict of interest form present for all members |  | | |  | |  | |  | |
| Has this committee met as per protocol? |  | | |  | |  | |  | |
| Minutes present for all meetings? |  | | |  | |  | | *Please specify* | |
| **ANNUAL REPORTS** | **Yes** | | | **No** | | **N/A** | | **Comments** | |
| Annual Progress Report (APR) |  | | |  | |  | | *Submitted in a timely manner? Where the DSURs approved by sponsor? Evidence that submitted to REC* | |
| Progress report to funder |  | | |  | |  | |  | |
| Other reports | |  |  | |  | |  | | |
| **INVESTIGATIONAL DEVICES** | | **Yes** | **No** | | **N/A** | | **Comments** | | |
| Name of device |  | | | | | | | | |
| Device Instruction Manual/ Management plan present? |  | | |  | |  | |  | |
| Investigator brochure present? |  | | |  | |  | | *List current version and Include all superseded versions* | |
| Evidence of annual review of IB from CI |  | | |  | |  | | *Evidence may be emails or IB log* | |
| Device Location |  | | |  | |  | | |  |  |  | | --- | --- | --- | | *Device ID* | *Serial number* | *Expiry date (if applicable)* | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  |   *Location of Devices (full address):* | |
| Label attached to device (if applicable) |  | | |  | |  | | *Has label been approved by REC and MHRA?* | |
| Is device accountability log up to date? |  | | |  | |  | | *Include details below:* | |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | *Device ID* | *Subject ID* | *Date of dispensing and staff member* | *Serial number (if applicable)* | *Date of return*  *(if applicable)* | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | | | | | | | | | | |
| Evidence of training on equipment in training log? |  | | |  | |  | |  | |
| **NON INVESTIGATIONAL MEDICAL EQUIPMENT DEVICES** | **Yes** | | | **No** | | **N/A** | | **Comments** | |
| Is any equipment provided to the sites? |  | | |  | |  | |  | |
| 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) |  | | |  | |  | | |  |
| Was equipment calibrated at start of study? |  | | |  | |  | | |  |
| Equipment manual/instructions in place? |  | | |  | |  | | |  |
| **CLOSE OUT DOCUMENTATION** | **Yes** | | | **No** | | **N/A** | | **Comments** | |
| Have the end of trial criteria been met? |  | | |  | |  | | *Please insert EOT definition* | |
| Has the study been extended? |  | | |  | |  | | *If yes please specify which amendment this relates to and confirm sponsor, REC and MHRA have been informed* | |
| All Laboratory analysis performed? |  | | |  | |  | |  | |
| Remaining Tissue transferred to HTA approved lab or destroyed? |  | | |  | |  | | *Protocol will state what should happen to tissue at the end of the study* | |
| REC End of trial notification and acknowledgement |  | | |  | |  | | *Dates documents sent, received and acknowledged* | |
| MHRA End of trial notification and acknowledgement |  | | |  | |  | |  | |
| Clinical study report present |  | | |  | |  | | *Date JRMO approved*  *Date sent to MHRA and Ethics and all acknowledgements* | |
| *Date sent to MHRA and Ethics and all acknowledgements* | |
|  | |
| Results published on a public website |  | | |  | |  | | *State which website and date results published* | |
| Archiving arrangements (including database/CRFs) |  | | |  | |  | |  | |

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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 | |  |
| Are all **AEs** accounted for and recorded in the CRF? | | | | | | Yes  No | | |  |
| Have all AEs been followed up and closed? | | | | | | Yes  No | | |  |
| Are all **SADEs** accounted for and recorded in the CRF? | | | | | | Yes  No | | |  |
| Have all SADEs been followed up and closed? | | | | | | Yes  No | | |  |
| Have all USADEs been recorded in CRF and reported to the sponsor? | | | | | | Yes  No | | |  |
| Have any device deficiencies been recorded and reported? | | | | | | Yes  No | | |  |
| **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 | |  |
| Are all **AEs** accounted for and recorded in the CRF? | | | | | | Yes  No | | |  |
| Have all AEs been followed up and closed? | | | | | | Yes  No | | |  |
| Are all **SADEs** accounted for and recorded in the CRF? | | | | | | Yes  No | | |  |
| Have all USADEs been followed up and closed? | | | | | | Yes  No | | |  |
| Have any device deficiencies been recorded and reported? | | | | | | 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** |
| Is there an AE log present? |  |  |  | *This can be patient specific or a general log with all AEs* |
| Does the SAE log match the records from the sponsor? |  |  |  | *Log should included relatedness to device (SADEs)* |
| Has all SAEs and SADEs been reported to the sponsor and manufacturer? |  |  |  | *Please list evidence* |
| Were all SAEs and SADE forms signed by CI/PI/co-investigators? |  |  |  | *Assessment can also be via email* |
| Have all ASADEs and USADEs been recorded in CRF and reported to the sponsor and manufacturer? |  |  |  |  |
| Evidence of ASADEs and USADEs reported to the REC and MHRA from manufacturer? |  |  |  | *ASADEs need to be reported to MHRA only*  *USADEs need to be reported to REC and MHRA* |
| SAE reporting to MHRA as per initial approval |  |  |  | *This is usually 3 monthly and a condition mentioned in initial MHRA no objection letter. This is usually delegated to manufacture. Please insert deatil* |
| Device events log present? |  |  |  |  |
| Device deficiency log present? |  |  |  |  |
| Device recalls or correspondence related to safety |  |  |  |  |
| All pregnancies reported, accounted and followed up in the CRF |  |  |  |  |
| Templates of all reporting forms present? |  |  |  | *Clinical investigation reporting form*  *Pregnancy reporting form* |

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| 9. MONITORING AND AUDIT | | | | |
| **This visit** | **Yes** | **No** | **N/A** | **Comment** |
| Central Monitoring preformed as per monitoring plan |  |  | Please check monitoring plan for details, comment on what should be occurring, if evidence can be seen that this has been completed or not. |  |
| 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* |
| Has this study been audited? |  |  |  |  |
| Has this study been inspected? |  |  |  |  |

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| 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 | | | |
| GCP & Governance Manager | **Name:**  **Email:** | Date | Signature |