**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| Withdrawn |  | *Number of participants who withdrew or were withdrawn from the study before reaching the end of the study per protocol.* |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** |
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| **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** |
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| **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 |
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| **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 | [ ]  | [ ]  | [ ]  |

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| *Device ID* | *Serial number*  | *Expiry date (if applicable)* |
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*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:* |
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| *Device ID* | *Subject ID* | *Date of dispensing and staff member*  | *Serial number (if applicable)* | *Date of return**(if applicable)* |
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| 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 |
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| **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 |