**Joint Research Management Office**

***Trial Master File (TMF) Monitoring Form - for Multi-Centre Studies***

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| 1. **GENERAL INFORMATION**
 |
| **Study Title:** | **Sponsor:** |
| **Study IRAS number:** | **CI:** |
|  | 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: |  |
| Next scheduled visit date (refer to study monitoring plan): | Name of the monitor:  |
| 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| Withdrawn |  | *Number of participants who withdrew or were withdrawn from the study before reaching the end of the study per protocol.* |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** |
|  | CI meet? | Yes[ ]  No[ ]  |  *Insert detail- face to face etc.* |
| **Does the CI 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** |
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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 (Date)** | **MHRA approval (Date)** | **REC approval (Date)** | **Present in the TMF?** | **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 TMF?** | **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 [ ]  |

| **Documents Present in Study Records** |
| --- |
| **SPONSORSHIP APPROVAL** | **Yes** | **No** | **N/A** | **Comments** |
| 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* |
| Permission to recruit email | [ ]  | [ ]  | [ ]  |  |
| Confirmation of Capacity and Capability | [ ]  | [ ]  | [ ]  |  |
| Peer review form  | [ ]  | [ ]  | [ ]  |  |
| Risk assessments | [ ]  | [ ]  | [ ]  |  |
| Pharmacy provisional approval | [ ]  | [ ]  | [ ]  |  |
| Pharmacy Final approval  | [ ]  | [ ]  | [ ]  |  |
| Clinical Physics approval | [ ]  | [ ]  | [ ]  |  |
| Correspondence relating to JRMO set up phase | [ ]  | [ ]  | [ ]  |  |
| Other relevant approvals (please specify) | [ ]  | [ ]  | [ ]  |  |
| **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 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** | **Yes** | **No** | **N/A** | **Comments** |
| Amendment log present | [ ]  | [ ]  | [ ]  | *Was the log up to date?* |
| Protocol amndments v non as per SMR |  |  |  |  |
| Summary of all amendments (substantial and non-substantial) | [ ]  | [ ]  | [ ]  | Amendment type, number and date:Peer review/ statistical review (where applicable):JRMO authorisation for submission:REC submission letter:REC approval:MHRA submission letter:MHRA approval:HRA approval(may be joint with REC approval):JRMO acknowledgement:List approved documents present in ISF |
| Has the study been ‘temporarily halted’  | [ ]  | [ ]  | *If Yes indicate here which amendments reflects this* |
| Have there been any Urgent Safety Measures? |  |  |  |
| Expedited safety information received and filed |  |  |  |
| **Recruitment** | **Yes** | **No** | **N/A** | **Comments** |
| Enrolment log present | [ ]  | [ ]  | [ ]  |  |
| **CONTRACTS AND FUNDING** | **Yes** | **No** | **N/A** | **Comments** |
| Indemnity/insurance letters | [ ]  | [ ]  | [ ]  | *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* |
| Periodic reports to the funder | [ ]  | [ ]  | [ ]  | *List*  |
| IMP provider agreement | [ ]  | [ ]  | [ ]  | *Specify name of Supplier/s and duration* |
| Technical agreement | [ ]  | [ ]  | [ ]  | *Specify name of parties and duration* |
| Laboratory agreement  | [ ]  | [ ]  | [ ]  |  |
| Device / equipment loan/gift agreement | [ ]  | [ ]  | [ ]  |  |
| Any other contracts | [ ]  | [ ]  | [ ]  |  |
| **DATA MANAGEMENT** | **Yes** | **No** | **N/A** | **Comments** |
| 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* |
| Have CRFs been completed and submitted appropriately? | [ ]  | [ ]  | [ ]  |  |
| 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? | [ ]  | [ ]  | [ ]  |  |
| 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.*  |
| **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* |
| Documentation on who has Access to database | [ ]  | [ ]  | [ ]  |  |
| Training on database for all users | [ ]  | [ ]  | [ ]  |  |
| Any other database related issues (interaction with other systems, audit studies) | [ ]  | [ ]  | [ ]  |  |
| **STUDY PERSONNEL** |
| Coordinating team delegation log present | [ ]  | [ ]  | [ ]  |  |
| Training log present | [ ]  | [ ]  | [ ]  |  |
| **All documentation present and correct? Yes** [ ]  **No[ ]**  for details see below |
| **Name** | **On Delegation log?** | **Role within the study** | **CV***(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** |
| 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 sites?* |
| IMP dossier | [ ]  | [ ]  | [ ]  |  |
| Named Sponsor Pharmacist  | [ ]  | [ ]  | [ ]  | *Provide name and address* |
| Copy of the MA IMP – importer’s manufacturing authorisation  | [ ]  | [ ]  | [ ]  |  |
| QP declaration  | [ ]  | [ ]  | [ ]  |  |
| TSE statements  | [ ]  | [ ]  | [ ]  |  |
| IMP Management plan  | [ ]  | [ ]  | [ ]  | *List all versions* |
| Pharmacy manual  | [ ]  | [ ]  | [ ]  | *List all versions* |
| Sample label attached to IMP(s)  | [ ]  | [ ]  | [ ]  |  |
| Prescription template | [ ]  | [ ]  | [ ]  |  |
| Labs |
| Name and address and role of each lab used | [ ]  | [ ]  | [ ]  |  |
| UKAS accreditation certificate and letters | [ ]  | [ ]  | [ ]  |  |
| 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? | [ ]  | [ ]  | [ ]  |  |
| **Standard operating procedures (SOPs)** |
| SOP log | [ ]  | [ ]  | [ ]  |  |
| **Name of SOP** | **Version** | **Review date** | **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** |
| Development Safety Update Report | [ ]  | [ ]  | [ ]  | *Please list the reports year by year including the date of submission to REC/MHRA**Submitted in a timely manner? Where the DSURs approved by sponsor? Evidence that submitted to REC and MHRA?* |
| Annual Progress Report | [ ]  | [ ]  | [ ]  | *Submitted in a timely manner? Where the DSURs approved by sponsor? Evidence that submitted to REC*  |
| Progress report to funder | [ ]  | [ ]  | [ ]  |  |
| **MEDICAL EQUIPMENT AND DEVICES** | **Yes** | **No** | **N/A** | **Comments** |
| Equipment log present | [ ]  | [ ]  | [ ]  |  |
| Is any equipment provided to the sites? | [ ]  | [ ]  | [ ]  |  |
| Equipment manual/instructions in place? | [ ]  | [ ]  | [ ]  |  |
| Serial numbers of all devices and equipment listed in log?  | [ ]  | [ ]  | [ ]  |  |
| Evidence of training on equipment in training log?  | [ ]  | [ ]  | [ ]  |  |
| **CORRESPONDENCE** | **Yes** | **No** |  |
| 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** |
| Have the end of study 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 |  |  |  |  |
| Archiving arrangements (including database/CRFs) | [ ]  | [ ]  | [ ]  |  |

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| 5. SITE/COUNTRY AND CENTRAL FACILITY INFORMATION (delete as applicable) |
| **If UK only:** |
| **Site number:** | **Site name:** |
| **Documents** |  | **Comments:** |
| CTA /NCC agreement present? | Yes[ ]  No[ ]  N/A[ ]  | *Please list date and authorised signatories* |
| Listed as site on REC forms | Yes[ ]  No[ ]  N/A[ ]  |  |
| ARSAC License | Yes[ ]  No[ ]  N/A[ ]  | *State if n/a* |
| Central Imaging transfer test performed? | Yes[ ]  No[ ]  N/A[ ]  |  |
| Emergency contact test performed? | Yes[ ]  No[ ]  N/A[ ]  |  |
| NHS permission or R&D approval | Yes[ ]  No[ ]  N/A[ ]  | *Please list date and authorised signatories* |
| PI CV and GCP training | Yes[ ]  No[ ]  N/A[ ]  | *Please list dates* |
| NHS /CPA accredited lab – Certificate, letter and CV of manager | Yes[ ]  No[ ]  N/A[ ]  | *Please list documents* |
| Deviation log present? | Yes[ ]  No[ ]  N/A[ ]  |  |
| **SITE MONITORING** |
| Study SIV template present | Yes[ ]  No[ ]  N/A[ ]  | *Specify version* |
| Template monitoring forms present | Yes[ ]  No[ ]  N/A[ ]  | *Specify version* |
| Monitoring plan present and signed | Yes[ ]  No[ ]  N/A[ ]  | *Specify version* |

***PLEASE COPY THIS TABLE FOR MULTIPLE UK SITES***

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| **MONITORING PER SITE** |
| **Site number** | **Monitoring reports /summary’s** | **SIV reports present –if yes date** | **Comments** |
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| **If International:** |
| **Site number:** | **Country/Site name:** |
| **Documents** |  | **Comments:** |
| CA approval | Yes[ ]  No[ ]  N/A[ ]  | *Please list date and authorised signatories* |
| Ethical approval | Yes[ ]  No[ ]  N/A[ ]  | *Please list date and authorised signatories* |
| CTA /NCC agreement present? | Yes[ ]  No[ ]  N/A[ ]  | *Please list date and authorised signatories* |
| Deviation log present? | Yes[ ]  No[ ]  N/A[ ]  |  |
| **SITE MONITORING** |
| Study SIV template and SIV reports present? | Yes[ ]  No[ ]  N/A[ ]  | *Specify version and dates* |
| Template monitoring forms present | Yes[ ]  No[ ]  N/A[ ]  | *Specify version* |
| Country Monitoring plan | Yes[ ]  No[ ]  N/A[ ]  | *Specify version* |

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| **MONITORING PER COUNTRY** |
| **Country** | **Monitoring reports /summary’s** | **SIV reports present –if yes date** | **Comments** |
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| **Central Facility** |
| **Facility name:** | **Role and activity being performed:** |
| **Documents** |  | **Comments:** |
| Agreement present? | Yes[ ]  No[ ]  N/A[ ]  | *Please list date and authorised signatories* |
| Deviation log present? | Yes[ ]  No[ ]  N/A[ ]  |  |
| **CENTRAL FACILITY MONITORING** |
| SIV report present? | Yes[ ]  No[ ]  N/A[ ]  | *Specify version and dates* |
| Monitoring reports present | Yes[ ]  No[ ]  N/A[ ]  | *Specify version and dates* |
| Correspondence present? | Yes[ ]  No[ ]  N/A[ ]  | *Please summarise* |

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| **6. Deviations** | **Yes** | **No** | **N/A** | **Comments** |
|  | [ ]  | [ ]  | [ ]  |  |
| Is a main study wide deviation log present? | [ ]  | [ ]  |  *insert if site specific / facility specific logs are used instead* |
| Have any deviations been logged? | [ ]  | [ ]  | [ ]  |  |
| Were any of these potential serious breaches? | [ ]  | [ ]  | [ ]  |  |
| Who (individual or committee) has oversight of deviations? | *Insert*  | *Consider who looks for trends and patterns? Can you see any obvious trends to highlight? E.g. multiple PID breaches at one site* |

| **7. PHARMACOVIGILIANCE** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Blank copy of **SAE** form | [ ]  | [ ]  | [ ]  | *Please specify name, version number and date of the document(s)* |
| SAE log present | [ ]  | [ ]  | [ ]  | *Is the log up to date?* |
| Does the SAE log present match the Sponsor log? | [ ]  | [ ]  | *Comment* |
| Completed SAE forms | [ ]  | [ ]  | [ ]  |  |
| Were all SAE forms signed by CI/PI/Co-Investigators?  | [ ]  | [ ]  | [ ]  |  *Evidence that SUSAR has been submitted to MHRA, REC and distributed to all sites?* |
| SUSAR reports | [ ]  | [ ]  | [ ]  |  |
| Drug recalls or correspondence related to safety | [ ]  | [ ]  | [ ]  |  |
| All pregnancies reported, accounted and followed up in the CRF? | [ ]  | [ ]  | [ ]  |  |

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| 8. 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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| 9. SUMMARY OF FINDINGS AND ACTIONS  |
| **No** | **Finding type (please see key for details)** | **Summary of finding** | **Corrective action and person carrying out this action** | **Severity****(Critical, Major, Other)** | **Proposed timeline to resolve** | **Date action completed** **(if not completed state this)** |
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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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| 10. SIGNATURES AND REVIEW |
| Completed by: |
| Study Monitor  | **Name:** **Email:**  | Date:  | Signature |
| Reviewed by  |
| Research Governance and GCP Manager | **Name:** **Email:**  | Date  | Signature |