Performing a Monitoring Visit

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| Recruitment | ✓ |
| Subject and pre-screening logs complete |  |
| Number of participants verified as required by monitoring report |  |
| Participant numbers add up (e.g., consented = screen fails + randomised, randomised = ongoing + completed + withdrawn) |  |
| Study team have updated CPMS within last month and numbers are accurate |  |
| Numbers at site reconcile with numbers in eCRF/database |  |
| Documentation | ✓ |
| Investigator site file (ISF) is up to date (as required by SDV plan) |  |
| Amendments have been implemented and correct document versions are in use |  |
| All study documentation is appropriately version controlled |  |
| All signature fields on contracts/protocols/IBs/charters/other documents are complete |  |
| Study committees are being held at appropriate time points according to protocol/charter |  |
| Study Blinding | ✓ |
| Check if unblinding has taken place at site (review audit trail/confirm with programmer if electronic) |  |
| If unblinding has occurred documented check documentation as per protocol |  |
| Blinded and unblinded members of study team are clearly delegated (if applicable) |  |
| No unblinded information is available to blinded individuals |  |
| Code breaks are intact |  |
| Access to unblinding system confirmed by site team where required for emergency unblinding |  |
| Randomisation and Dose Assessment | ✓ |
| Compliance with method of randomisation described in protocol |  |
| Correct treatment received according to randomised allocation (verify with source) |  |
| Ensure essential documents retained for reconstruction of process (especially if paper based) |  |
| Planned dose of IMP recorded in medical notes |  |
| Dose calculation correct (where applicable) |  |
| Dose of IMP received by participant as per protocol |  |
| Participant compliance documented (if required by protocol/SDV plan) |  |
| Safety | ✓ |
| All adverse events identified and recorded as per protocol (verified with medical records) |  |
| All adverse events assessed as per protocol (seriousness, severity, expectedness, relatedness) |  |
| Assessments conducted by correctly delegated investigator |  |
| All SAEs reported to Sponsor within 24 hours of study team becoming aware |  |
| AEs documented in medical notes |  |
| Number of SAEs recorded by site reconciled with ACCORD PV database |  |
| Number of SAEs recorded by site reconciled with eCRF/database (if applicable) |  |
| AEs/SAEs verified by source according to SDV plan |  |
| Approved version of RSI on file for assessment of ARs |  |
| Investigator oversight of SUSAR notifications documented (if applicable) |  |
| Investigator oversight of study specific test results (e.g., lab, ECG, scans) |  |
| Concomitant meds recorded as per protocol |  |
| Concomitant meds reconciled with AE log/medical history |  |
| No use of protocol described prohibited medications (verified with medical records) |  |
| IMP Accountability and Storage | ✓ |
| Shipping records verified and reconciled with site level accountability log |  |
| Site staff receiving and processing shipment delegated to do so |  |
| Storage of IMP and returns secure, separate from other medicines, segregated from each other, as per protocol |  |
| Labelling of IMP correct as per protocol |  |
| Temperature logs reviewed for excursions at pharmacy/ward level (if required by SDV plan) |  |
| In event of excursion affected IMP quarantined until action required confirmed by Sponsor |  |
| Temperature monitoring equipment is calibrated |  |
| Accountability logs complete (site and participant level) |  |
| Stock counted (if required by SDV plan) |  |
| Returns counted/reconciled (if required by SDV plan) |  |
| All IMP accounted for |  |
| All members of staff accountable for IMP correctly delegated |  |
| Prescription of correct IMP by delegated Investigator post eligibility sign off |  |
| Dispensing process followed – dispensing and dispensing check documented |  |
| Correct treatment dispensed according to randomisation (verify with randomisation source) |  |
| All members of staff dispensing IMP delegated to do so |  |
| Expiry date checked – medication will not expire prior to end of course dispensed |  |
| Any expired medication/packs which would expire prior to end of course in quarantine |  |
| Destruction of IMP documented (to include individual pack IDs) |  |
| Sponsor approval for destruction of IMP (where applicable) |  |
| Pharmacy file complete and correct versions of study documents present |  |
| Pharmacy instructions correct |  |
| Where IMP stored at ward level – pharmacy oversight documented |  |
| Eligibility | ✓ |
| Inclusion criteria verified by source |  |
| Exclusion criteria verified by source |  |
| Eligibility sign off by delegated investigator |  |
| Investigator oversight of all eligibility related results prior to eligibility sign off |  |
| Eligibility sign off completed prior to dosing |  |
| Confirmation of eligibility reflected in medical/research notes |  |
| Evidence of GP letter sent |  |
| Informed consent | ✓ |
| Version of informed consent form (ICF) is correct for time of consent |  |
| All fields completed on ICF |  |
| All boxes on ICF initialled by participant |  |
| Participant has signed own consent form |  |
| Participant has dated own consent form |  |
| Consenter is correctly delegated on delegation log and signed off by PI prior to task |  |
| Participant name and date of consent matches consent and subject status log |  |
| Consent process is documented in medical/research notes |  |
| Participant was allowed protocol defined time to consider PIS |  |
| Consent was taken prior to any study specific procedures |  |
| Participation in clinical trial is documented/flagged in medical notes |  |
| ICF present for each participant |  |
| Data QC and Storage | ✓ |
| Data in database matches exactly data recorded in pCRF (where required by SDV plan) |  |
| Source data is stored securely, backed up and cannot be altered without an audit trail |  |
| Study data is stored securely, backed up and cannot be altered without an audit trail |  |
| Calendar, CRF completion and source data verification | ✓ |
| Date of study visit verified with medical/research notes |  |
| Study assessments conducted at time points defined in protocol |  |
| Site staff performing assessments are delegated to do so |  |
| Equipment used to perform study assessments is calibrated/maintained (where applicable) |  |
| Participant exists (verify with medical notes) |  |
| Data entered in CRF is legible (paper only) |  |
| Data entered in CRF in a timely manner (paper and electronic) |  |
| Data entered is complete |  |
| Site staff entering CRF data are delegated to do so |  |
| Version of CRF used is correct at time of data collection |  |
| No confidential identifiers have left investigator site without consent |  |
| CRF data points verified by source as required by SDV plan |  |
| Record and raise any data queries/ discrepancies identified with source data |  |
| Any changes made to key data points are explicable and made in a GCP compliant manner (review audit trail for eCRF) |  |
| Protocol/Regulatory Compliance | ✓ |
| All non-compliances documented as per protocol |  |
| All non-compliances assessed for potential impact on safety/outcomes |  |
| Number of deviations recorded at site reconciled with QA ACCORD database |  |
| Number of violations recorded at site reconciled with QA ACCORD database |  |
| All violations/serious breaches reported within 72/24 hours of study team becoming aware |  |
| Compliance with protocol defined deviation reporting schedule |  |
| CAPA from violations/serious breaches completed |  |
| Delegation log, CVs, GCPs and staff training | ✓ |
| All fields required on delegation log complete |  |
| All tasks on delegation log delegated |  |
| Individual tasks are appropriate for study role (note medic only tasks) |  |
| Any members of staff who have left the team have end dates added |  |
| All members of staff on the delegation log have a CV filed |  |
| All members of staff on the delegation log have evidence of GCP training filed |  |
| GCP training evidence is in date (Check Board/Trust policy for expiry) |  |
| All members of staff on the delegation log have study protocol training documented |  |
| Facilities and Resources | ✓ |
| Samples taken according to protocol |  |
| Sample storage correct as per protocol/sample handling instructions |  |
| Temperature logs reviewed for excursions (where applicable) |  |
| Temperature monitoring equipment is calibrated |  |
| Sample processing documented and correct according to protocol/handling instructions |  |
| Processing equipment calibrated/maintained and records available |  |
| Location of samples clearly documented in ISF |  |
| Sample tracking logs present and complete |  |

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| Samples counted; all samples accounted for |  |
| If consent optional consent in place for all samples |  |
| Sample destruction documented |  |
| Lab accreditations/ACCORD audit certificate in place |  |
| Study specific checks (list study specific checks identified in protocol/SDV plan) | ✓ |
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