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| **Site Initiation Report** | | | | | | | | | |
| **Study Title:** | | | | | | | | | |
| **Site Number:** | | | | | **Site:** | | | | |
| **Sponsor**  **(Queen Mary University of London or**  **Barts Health NHS Trust)** | | | | |  | | | | |
| **Date of Initiation Visit:** | | | | | **PI:** | | | | |
| **Report Produced on:** | | | | |  | | | | |
| **Follow up correspondence sent on:** | | | | |  | | | | |
| **Attendees: (to include names and titles of Principal Investigator (PI), pharmacist, Chief Investigator (CI) [where feasible], research team i.e. research nurse, person delegated to deliver Site Initiation Visit (SIV) if not the CI, Trial manager/coordinator.** | | | | | | | | | |
| **TOPIC COVERED** | | | | | **YES** | **NO** | **N/A** | **COMMENTS / ISSUES RAISED** | |
| **GENERAL** | | | | | | | | | |
| Has the final version of the protocol been discussed (indicate date and version number)? | | | | |  |  |  |  | |
| Objectives | | | | |  |  |  |  | |
| Study Design | | | | |  |  |  |  | |
| Inclusion/Exclusion | | | | |  |  |  |  | |
| Screening, enrolment and randomisation procedures discussed?  Eligibility checks by physician prior to randomisation?  *Screening logs present in site file?*  *ID logs used?*  Randomisation Standard Operating Procedure (SOP) present in Site File and discussed (state version and date in comments) | | | | |  |  |  |  | |
| Informed Consent documentation and process (Please indicate current version of Participant Information Sheet (PIS) and Informed Consent Form (ICF) in comments box). Have all informed consent processes been addressed including when re-consenting participant is necessary. | | | | |  |  |  |  | |
| Study Procedures | | | | |  |  |  |  | |
| Unblinding procedures (if applicable). Unblinding SOP present in Site File and discussed (state version and date in comments) | | | | |  |  |  |  | |
| Last dose and follow-up discussed? | | | | |  |  |  |  | |
| Roles, responsibilities and Delegation log | | | | |  |  |  |  | |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Name on Delegation Log | Role | Date Log Signed | CV (date of signature) | Good Clinical Practice (GCP) training certificate (date of last training) | Appropriate study specific training given and added to Training log | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | | | | | | | | | | |
| Laboratory Requirements | | | | |  |  |  |  | |
| Sites responsibility for collection and maintenance of essential documents | | | | |  |  |  |  | |
| Has the investigator defined what will be considered source data on the source data list in the Investigator Site file (ISF)? | | | | |  |  |  |  | |
| Create list of source data | | | | |  |  |  |  | |
| Is the Investigator aware of their responsibilities regarding direct access to the source data for each patient and how this will be achieved? | | | | |  |  |  |  | |
| Have all site staff had sufficient Case Report Form (CRF) completion and correction training? | | | | |  |  |  | Date and version of the CRF | |
| Has the study database been discussed and database plan been agreed? | | | | |  |  |  |  | |
| Has the process for Sponsor Audits, Regulatory Inspections been discussed? | | | | |  |  |  |  | |
| Study Opening Procedure | | | | |  |  |  |  | |
| Has all required Study/Protocol specific training been completed? Please include details of any investigator training if applicable.  I.e. specific procedures, device/equipment. | | | | |  |  |  |  | |
| **PHARMOCOVIGILANCE (PV) / Safety Reporting** | | | | |  |  |  |  | |
| Have the investigator and other relevant trial staff been trained in the relevant Joint Research Management Office PV SOP? | | | | |  |  |  |  | |
| Is the Investigator aware of the emergency code break procedures (if applicable) | | | | |  |  |  |  | |
| Has the emergency out of hour’s telephone number been tested? | | | | |  |  |  | Date when emergency out of hour tested | |
| Has the safety profile, Investigators Brochure (IB) or Summary of Product Characteristics (SmPC) for the Investigational Medicinal product (IMP)/ device been discussed? | | | | |  |  |  | Indicate version and date of all IB/SMPC(s) | |
| Has the Research Safety Information (RSI) location been discussed, for the PI to make the Suspected Unexpected Serious Adverse Reaction (SUSAR)/Unanticipated Serious Adverse Device Effect (USADE) relatedness and expected decisions? | | | | |  |  |  | Ensure RSI clearly defined (document and section) | |
| Is the research team aware of what is day zero for reporting Serious Adverse Event (SAE) to the Sponsor? | | | | |  |  |  | (Day zero is the day the site notifies the CI, who is delegate PV on behalf of the sponsor) | |
| Has the requirement for the PI to record of AEs in source date (patient notes or e-notes) and in the CRFs been discussed | | | | |  |  |  |  | |
| Has the requirement for a physician to make the clinical assessment of Adverse Event (AE) been discussed? | | | | |  |  |  |  | |
| Has the SAE form been reviewed and discussed? Including the requirement for a medical assessment by a physician before it is sent to the sponsor? | | | | |  |  |  |  | |
| Has pregnancy reporting and the pregnancy form been discussed and evidence of copy in ISF? | | | | |  |  |  |  | |
| Have study specific PV SOPs been discussed (if applicable) | | | | |  |  |  | Date and version of SOP | |
| Has the procedure of notification of serious breaches of GCP or the study protocol been discussed? Copy of JRMO SOP 37 - Reporting serious breaches of GCP or study protocol in the Site file? | | | | |  |  |  |  | |
| Clinical Investigations only – have the procedures for assessing and reporting Device Deficiencies been discussed? | | | | |  |  |  |  | |
| **PHARMACY – CTIMPs only** | | | | | | | | | |
| Dosing Schedule discussed and clear on prescription? | | | | |  |  |  |  | |
| Dispensing. Have all procedures for allocating treatment or patient numbers been reviewed? (E.g. IVRS)? | | | | |  |  |  |  | |
| Method of IMP accountability discussed | | | | |  |  |  |  | |
| Storage – have the storage conditions been checked? Arrangements for drug storage and accountability in place with pharmacy?  Adequate storage facilities (security, temperature) confirmed? | | | | |  |  |  | Date when storage conditions checked, including quarantine area. | |
| Ensure the below are present and discussed; Sample of labels  Investigator’s brochure  Shipping records in the pharmacy file | | | | |  |  |  |  | |
| Destruction / Return policy discussed? | | | | |  |  |  |  | |
| Amount IMP received | | | | |  |  |  |  | |
| Ordering IMP process discussed.  Contact details for sponsor pharmacist discussed | | | | |  |  |  |  | |
| Pharmacy manual | | | | |  |  |  |  | |
| Study-specific prescriptions present and reviewed by Sponsors Pharmacy representative? | | | | |  |  |  |  | |
| Unblinding procedures (if applicable). Unblinding SOP present in pharmacy file (state version and date in comments) and discussed. | | | | |  |  |  |  | |
| Arrangements for drug storage and accountability in place with pharmacy? (Security, temperature) confirmed? | | | | |  |  |  |  | |
| Have required pharmacy personnel completed the delegation log, provided current signed CV and provided evidence of recent GCP training (within 2-years). Include details of CVs and training certificates present and date of signature/training) | | | | |  |  |  |  | |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | Name on Delegation Log | Role | Date Log Signed | CV (date of signature) | GCP training certificate (date of last training) | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | | | | | | | | | | |
| **Investigational Devices – Clinical Investigations only** | | | | | | | | | |
| Instructions for Use discussed | | | | |  |  |  |  | |
| Confirmation on who can use the device | | | | |  |  |  |  | |
| Storage requirements and location | | | | |  |  |  |  | |
| Installation, calibration, validation requirements | | | | |  |  |  |  | |
| Maintenance requirements | | | | |  |  |  |  | |
| Sterilisation or cleaning requirements | | | | |  |  |  |  | |
| Safety requirements (including electrical safety and radiation safety etc.) | | | | |  |  |  |  | |
| Principal Investigator responsibilities | | | | |  |  |  |  | |
| **MONITORING** | | | | | | | | | |
| Visit log reviewed (and signed) | | | | |  |  |  |  | |
| Site monitoring procedures  -notice required; who to contact; space required for monitor. Requirement for the PI to be available to meet the monitor | | | | |  |  |  |  | |
| On-site monitoring  -PI/Co-I to be met with; Patient notes/source data | | | | |  |  |  |  | |
| Sponsor requirement to close monitoring findings within a given timeframe of monitoring report | | | | |  |  |  |  | |
| **PATIENT RECRUITMENT** | | | | | | | | | |
| Enrolment strategy (MDT, Clinics?) Consider patient pathway | | | | |  | | | | |
| Referrals (How, where from?) | | | | |  | | | | |
| Patients expected / year | | | | |  | | | | |
| Currently any potentially eligible patients | | | | |  | | | | |
| **STUDY PERSONNEL AND FACILITIES** | | | | | | | | | |
| Has the PI, study site, or its personnel been audited or inspected within the last 2 years?  -If yes, provide comment | | | | | Please specify who and when:  Findings: | | | | |
| Have arrangements been made for appropriate cover during any investigator or other site staff absences? Is this documented in the site file with contact details? | | | | | Specify PI alternative cover. | | | | |
| Will any additional facility be used for trial procedures?  -If yes, specify location(s) and intended use; Visit Facility; Facility fit for intended purpose | | | | | Please specify the additional facilities? | | | | |
| **SITE FILE / TRIAL MATERIALS** | | | | | | | | | |
| Site File Present? | | | | |  |  |  |  | |
| Were essential document collected during this visit for the TMF / Sponsor File? | | | | | List any documents: | | | | |
| Is the Investigator aware of their responsibility to maintain documentation including correspondence in the Investigator site file? | | | | |  | | | | |
| Does the site have all staff facilities and equipment to perform the trial according the trial protocol? | | | | |  | | | | |
| All necessary clinical trial materials received? (e.g.: lab kit, test strips? Devices, equipment) | | | | |  |  |  |  | |
| Have all specific materials procedures been explained? | | | | |  |  |  |  | |
| Has collection, handling and storage procedures of any samples to be taken from the trial been reviewed? Please state version and data of the lab manual if applicable? Have the requirements for Human Biological Sample Collection, Handling, Storage and Shipping been discussed?  Are there local SOPs to be considered?  Make sure labs have labels for clinical trial samples  Normal ranges have been described | | | | |  |  |  |  | |
| Have equipment and devices been calibrated? Who is the custodian of the equipment at the site? What training has been given on the study specific equipment? Is there evidence of a maintenance log in the Site File? | | | | |  |  |  |  | |
| Any study specific software? Has this been tested at site? Have the personnel been trained on the software (NB this is separate from CRFs and databases) | | | | |  |  |  |  | |
| Imaging – evidence of test scans to validate quality before activation? If the scans will be transferred to the lead site/central facility? Evidence that this has been tested. Any study specific imaging SOPs? | | | | |  |  |  |  | |
| End of trial procedures discussed? Including JRMO archiving requirements (25 years at site). JRMO SOP 20 – Archiving research studies discussed with study team? | | | | |  |  |  |  | |
| **Document** | | **Present** | **Not Present** | | **N/A** | **Comment** | | | |
| NHS Local Approval | |  |  | |  | Dated *DD-MM-YYYY* | | | |
| REC Approval | |  |  | |  |  | | | |
| MHRA Approval | |  |  | |  |  | | | |
| Contracts. Are all relevant contracts fully executed including financial agreements, service level agreements? | |  |  | |  | List all applicable contracts | | | |
| Current protocol | |  |  | |  | Version *X.X* Dated *DD-MM-YYYY* | | | |
| Current PIS and ICF | |  |  | |  | Version *X.X* Dated *DD-MM-YYYY* | | | |
| Current IB, IMPD, SmPC | |  |  | |  | Version *X.X* Dated *DD-MM-YYYY* | | | |
| Current Instructions for Use (Clinical Investigations only) | |  |  | |  |  | | | |
| All CVs- present and up-to date (incl. pharmacy staff) | |  |  | |  | CVs present: | | | |
| PI GCP certificate | |  |  | |  | Date of most recent training/refresher:  *DD-MM-YYYY* | | | |
| For other staff GCP documented on CVs | |  |  | |  |  | | | |
| Financial Disclosure Documents | |  |  | |  |  | | | |
| Laboratory Normal Ranges | |  |  | |  | Expiry Date *DD-MM-YYYY* | | | |
| Laboratory Accreditations Certificates | |  |  | |  | Expiry Date *DD-MM-YYYY* | | | |
| Signature and Delegation Log | |  |  | |  |  | | | |
| Screening, ID and Enrolment Logs | |  |  | |  |  | | | |
| Accountability logs (if using own) | |  |  | |  |  | | | |
| Trial specific prescriptions | |  |  | |  |  | | | |
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| **SUMMARY** | | | | | | | | | |
|  | **ACTION** | | | **PERSON RESPONSIBLE** | | | | | **TIME FRAME** |
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