**Final governance meeting report**

| **Short title** |  |
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| **ReDA Number** |  |
| **IRAS Number** |  |
| **Public Database Number** |  |
| **Chief Investigator (CI) name** |  |
| **Main Point of Contact** |  |
| **Location of meeting** |  |

| **Current visit date(s):** |  |
| --- | --- |
| **Attendees (names/roles):** | CI:  Trial Coordinator:  JRMO GCP manager:  JRMO Monitor:  JRMO Governance officer:  JRMO Contracts officer:  Clinical Physics representative:  Please insert any other members of the team present |

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|  | **Item** | **Comment** |
| **1.0** | **STUDY DETAILS** | |
| 1.1 | Clinical Investigation Plan discussed? | *NB this should include explanation of the study.*  *Confirm with Governance team they have a Protocol signed be CI and statistician?* |
| 1.2 | Any conflict of interest? | *Does the CI or any other investigator / collaborator have any personal involvement (e.g. financial, sharing holding, personal relationship, in the funding, drug device, or sponsor organization that may give rise to a conflict of inter*est?)  *Could this impact the Intellectual property? Is the person who is doing safety evaluation have a conflict of interest? (check against question 48 on IRAS form)* |
| 1.3 | Study specific Standard Operating Procedures (SOP)/ procedures discussed? | Please List: *(Completed/in progress / needed)*  *Distinguish between what is standard care and what is part of the protocol. Personnel authorised to take consent.*  *Always comment on:*   * *Randomisation procedure* (if electronic system validated)? *(I.e. not applicable etc.)* * Code break procedures in place, and tested (if electronic system validated)? |
| 1.4 | Questionnaires and additional tools:  Please specify | *Please list all in use including license status* |
| 1.5 | Number of sites and countries (if applicable) | *NHS and Non-NHS sites, international countries (EU and non-EU) sites* |
| 1.6 | Healthy volunteers? | *Discuss arrangements for healthy volunteers including non-NHS site set up, recruitment, reimbursements and data management.* |
| **2.0** | **Investigational Medical Device** |  |
| 2.1 | Please list all Investigational Devices and their manufacturers |  |
| 2.2 | Guidance available for installation, calibration and sterilization where applicable? |  |
| 2.3 | Clear process for recall of defective devices? | *Detail person responsible within sponsor* |
| 2.4 | Arrangements for updates to the Investigational Device documentation including the Investigator Brochure (IB). |  |
| 2.5 | Additional information for International sites: | *Is any input into the EU required?*  *Who is responsible for IMP management in international sites?*  *Outline any differences in IMP management if differing countries* |
| 2.6 | Clinical Physics Final approval | *Date if given/ actions if outstanding* |
| **3.0** | **CONTRACTS** |  |
| 3.1 | Contracts checklist competed and signed? | *Contract with manufacturer*  *Confirm the status of the agreement with the manufacturer. Include the supply and maintenance of the device, delegation of responsibilities and ownership of intellectual property arising from the device.* |
| 3.2 | Vendors | *Please list all vendors and associate details:*   |  |  |  | | --- | --- | --- | | *Name of vendor* | *Responsibility* | *Known/ Assessed/ preferred supplier.* | |  |  |  | |  |  |  | |  |  |  | |
| **4.0** | **DOCUMENTATION** | |
| 4.1 | Trial Master File (TMF) set up incompliance with SOP 45? | *Comment if Reviewed by Monitor [create separate report if needed] or present in meeting.*  *Comment if local (CTU for example) SOP is in place and being followed* |
| 4.2 | Will a study emergency “Out of Hours” contact be in place? | *Specify yes or no. Include justification if no* |
| 4.3 | If yes include testing details | *(Documented evidence in TMF)* |
| **5.0** | **AMENDMENTS** |  |
| 5.1 | Amendments process discussed (as per JRMO SOPs)? | *Sponsorship approval, Research Ethics Committee (REC) and MHRA, and site approval processes notifying sites of amendments,* |
| 5.2 | Discuss pending amendments | *Sponsor has authorisation to withhold sponsorship with conditions where substantial amendments are outstanding* |
| **6.0** | **DELEGATION** |  |
| 6.1 | CI-Sponsor agreement reviewed and discussed? |  |
| 6.2 | CI training completed and due? | *Insert date and date of next GCP and CI refresher due dates* |
| 6.3 | Research team’s training, and frequency of training discussed | *Frequency, by whom, training logs* |
| 6.4 | Adherence to Sponsor SOPs discussed? | *Ensure that the CI and team are aware of the JRMO SOPs, the website.* |
| 6.5 | Non-compliance discussed (as per SOP 31 Non-compliance)? |  |
| 6.6 | Sponsor has received a signed copy of the coordination delegation log |  |
| 6.7 | Role of accredited CTU discussed | *If applicable* |
| 6.8 | Role of National Coordinating Centers (NCCs) discussed | *International studies only* |
| **7.0** | **SITE ACTIVATION** |  |
| 7.1 | Site selection checklist agreed | *Use when selecting all Investigator Sites* |
| 7.2 | Site activation process discussed | *Ensure SOP 46 is followed* |
| 7.3 | Site activation checklist agreed | *Copy of study specific draft to be sent to JRMO* |
| 7.4 | Site Initiation Visit (SIV) presentation seen or discussed | *JRMO monitor and GCP manager to be invited to Barts/Local SIV as part of sponsor oversight and monitor training*  *Copy of study specific draft to be sent to JRMO* |
| 7.5 | Source data and record keeping discussed? | *Creation of source documentation list needed* |
| 7.6 | Training Log for all site staff and expectations of site-specific training | *See Training Log in SOP – Essential documents. This is NOT GCP training, but protocol and study delegated training.* |
| **8.0** | **MONITORING** |  |
| 8.1 | Monitoring plan present and signed by CI and Sponsor? | *Date and version. Does the proposed monitoring seem reasonable? Look at phase of study and treatment period.* |
| 8.2 | Adequate resources and staff to perform monitoring? |  |
| 8.3 | Monitor training appropriate? | *CV and training record to be collected. Are shadowed visits planned for inexperienced monitors?* |
| 8.4 | GCP inform CI’s team of Sponsor’s right to audit |  |
| **9.0** | **Safety Reporting** |  |
| 9.1 | Site safety arrangements discussed. | *Specify if any change to the Safety Reporting form have been agreed, discuss safety reporting for international sites (where applicable)*  *Confirmation of what constitutes day zero for reporting SAEs and Unexpected Serious Adverse Device Effects (USADEs)* *for all sites* |
| 9.2 | Confirm whether Safety Reporting will be delegated to the device manufacturer. |  |
| 9.3 | 24-hour unblinding tested? | *SOP required for unblinding.* |
| **10.0** | **ANNUAL REPORTS** |  |
| 10.1 | Reda updated with reminders? | *Date of first Annual Progress report (APR):* |
| 10.2 | Anticipated end date discussed | *Consider end of funding (see ReDA), correlates with REC/R&D end dates and study feasibility* |
| **11.0** | **DATA** |  |
| 11.1 | Data collection (Case Report Form (CRF)/eCRF) tools ready for use? | *Specify type, version, and date*  *Document if reviewed by JRMO (if lone investigator)* |
| 11.2 | Data collection (CRF/eCRF) tools signed by CI and statistician? |  |
| 11.3 | Case report forms reviewed by monitor (lone-Investigator trials only) |  |
| 11.4 | Database to be used? | *Specify type, version, and date* |
| 11.5 | Database ready and validation paperwork present? | *JRMO IT to confirm in writing* |
| 11.6 | Discussed frequency of data entry and data lock, end of trial. |  |
| **12.0** | **TRIAL COMMITTEES** |  |
| 12.1 | Trial committees confirmed  Charter drafted and agreed by Chair (minimum) and where possible whole committee | *List committees* |
| 12.2 | Members list confirmed in writing | *Frequency of meetings discussed and logged by GCP team* |
| 12.3 | CVs (signed and dated) and Conflict of interest forms collected | *Pending first meeting is acceptable* |
| **13.0** | **LABORATORIES** |  |
| 13.1 | Details of laboratories and collection areas: |  |
| 13.2 | Sample and laboratory collection SOPs in place and discussed? |  |
| 13.3 | Individual Laboratory approval received | *Central facilities- Laboratory manager and Head of lab* |
| 13.4 | Relevant material’s transportation/transport discussed | *Between locations between sites and between NHS/non-NHS sites*  *Detail courier to be used* |
| 13.5 | Supplying of kits to sites (where relevant) | *Discuss expiry dates on any kits – ensuring this is quality controlled before going to site. Inclusion of this in the site agreement. Consider expiration of blood test kits.* |
| 13.6 | End of trial destruction/banking of tissue discussed |  |
| **14.0** | **Other Central facilities** | *Consider central imaging review or collection, etc.* |
| 14.1 | List all central facilities |  |
| 14.2 | Imaging | *Test scans for quality and Personal Identifiable Data (PID) where scans/software is study specific. Test of transfer of scan to the lead site. Check that no PID is leaving site. SOP required.* |
| **15.0** | **EQUIPMENT** |  |
| 15.1 | List study specific equipment to be provided to sites other than Investigational Devices | *Provision of equipment discussed (loaned, gifted, bought, donated, standard care). Is the equipment standard at all sites?*  *Where loaned from another department, external party, Delivery receipts, returns process (where loaned),*  *Standard annual maintenance checks, unless specified otherwise by sponsor’s Clinical Physics representative.* |
| 15.2 | Equipment storage location and custodian identified |  |
| 15.3 | MHRA approval (where relevant) |  |
| 15.4 | Confirmation of equipment indemnity | *MIA where on loan or gifted* |
| 15.5 | Study specific SOP in place |  |
| 15.6 | Frequency of equipment maintenance recorded by monitors |  |
| 15.7 | Approved by sponsor’s Clinical Physics representative? |  |

| Summary of actions needed | | Person delegated |
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