**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 Good Clinical Practice (GCP) manager:  JRMO Monitor:  JRMO Governance officer:  JRMO Contracts officer:  Sponsor pharmacy representative :  Please insert any other members of the team present | |

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|  | **Item** | **Comment** |
| **1.0** | **STUDY DETAILS** | |
| 1.1 | Protocol discussed? | *NB this should include explanation of the study. If the protocol is about an area/specialism/ GCP manager and or Monitor is unfamiliar with a separate session should be arranged with the CI to ensure understanding.*  *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 organisation 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 | Phase 1 | *Phase 1 – is this in a hospital setting? Any non-NHS sites. Consider requirement for emergency provision – Crash/999. Grab bag - troll is required. Risk assessment is required in non-NHS sites.* |
| 1.7 | Healthy volunteers? | *If so, consider TOPs – over volunteer register. Risk assessment of emergency provision if not in NHS Trust (including if in Clinical Trials Unit (CTU)). Will they require copy of passport and driving license to confirm ID Contact the GP to confirm medical history – as no medical records? Look at Phase 1 accredited unit guidelines as exemplar of what the* *Medicines and Healthcare products Regulatory Agency (MHRA) look for in healthy volunteer studies.* |
| **2.0** | **Investigational Medicinal Product (IMP)** |  |
| 2.1 | Please list IMPs and Non-IMPs and their source and specify RSI | |  |  |  |  | | --- | --- | --- | --- | |  | *Name* | *Source* | *Reference Safety Information (RSI)* | | *IMP* |  |  |  | | *Non-IMP* |  |  |  | |
| 2.2 | Technical Agreement | *Technical Agreement needed- Yes/ No*  *Comment here on status of agreement*  *specialist pharmacist involved?* |
| 2.3 | IMP Management plan (co-ordination) | *Discuss* supply and management, *storage, temperature monitoring, standard stock, ordering, and receipt. If single site are, they merging IMP manual and management plan into one?* |
| 2.4 | IMP manual (site) |  |
| 2.5 | Clear process for recall defective IMP? | *Detail person responsible within sponsor* |
| 2.6 | Arrangements for Summaries of product characteristics (SmPC)/ Investigator Brochure (IB) updated |  |
| 2.7 | 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* |
| 2.8 | Sponsor Pharmacy representative Final approval | *Date if given/ actions if outstanding* |
|  | **CONTRACTS** |  |
|  | Contracts checklist competed and signed? |  |
|  | Vendors | *Please list all vendors and associate details:*   |  |  |  | | --- | --- | --- | | *Name of vendor* | *Responsibility* | *Known/ Assessed/ preferred supplier.* | |  |  |  | |  |  |  | |  |  |  | |
| **3.0** | **DOCUMENTATION** | |
| 3.1 | 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* |
| 3.2 | Will a study emergency “Out of Hours” contact be in place? | *Specify yes or no. Include justification if no* |
| 3.3 | If yes include testing details | *(Documented evidence in TMF)* |
| **4.0** | **AMENDMENTS** |  |
| 4.1 | Amendments process discussed (as per Joint Research Management Office (JRMO) SOPs)? | *Sponsorship approval, Research Ethics Committee (REC) and MHRA, and site approval processes notifying sites of amendments,* |
| 4.2 | Discuss pending amendments | *Sponsor has authorisation to withhold sponsorship with conditions where substantial amendments are outstanding* |
| **5.0** | **DELEGATION** |  |
| 5.1 | CI-Sponsor agreement reviewed and discussed? |  |
| 5.2 | Conditions of sponsorship and delegation resigned by CI? |  |
| 5.3 | CI training completed and due? | *Insert date and date of next GCP and CI refresher due dates* |
| 5.4 | Research team’s training, and frequency of training discussed | *Frequency, by whom, training logs* |
| 5.5 | Adherence to Sponsor SOPs discussed? | *Ensure that the CI and team are aware of the JRMO SOPs, the website.* |
| 5.6 | Non-compliance discussed (as per Non-compliance SOP)? |  |
| 5.7 | Sponsor has received a signed copy of the coordination delegation log |  |
| 5.8 | Role of accredited CTU discussed | *If applicable* |
| 5.9 | Role of National Coordinating Centers (NCCs) discussed | *International studies only* |
| **6.0** | **SITE ACTIVATION** |  |
| 6.1 | Site activation process discussed | *Ensure SOP 46 is followed* |
| 6.2 | Site activation checklist agreed | *Copy of study specific draft to be sent to JRMO* |
| 6.3 | 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* |
| 6.4 | Source data and record keeping discussed? | *Creation of source documentation list needed* |
| 6.5 | 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.* |
| **7.0** | **MONITORING** |  |
| 7.1 | 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.* |
| 7.2 | Adequate resources and staff to perform monitoring? |  |
| 7.3 | Monitor training appropriate? | *CV and training record to be collected. Are shadowed visits planned for inexperienced monitors?* |
| 7.4 | GCP inform CI’s team of Sponsor’s right to audit |  |
| **8.0** | **PHARMACOVIGILANCE (PV)** |  |
| 8.1 | Pharmacovigilance arrangements discussed. | *Specify if any change to Serious Adverse Event (SAE) form has been agreed, discuss PV reporting for international sites (where applicable)*  *Confirmation of what constitutes day zero for reporting SAEs and* *Suspected Unexpected Serious Adverse Reactions (SUSAR) for all sites* |
| 8.2 | 24-hour unblinding tested? | *SOP required for unblinding.* |
| **9.0** | **ANNUAL REPORTS** |  |
| 9.1 | Reda updated with reminders? | *Date of First Development Safety Update Report (DSUR):*  *Date of first Annual Progress report (APR):* |
| 9.2 | Anticipated end date discussed | *Consider end of funding (see ReDA), correlates with REC/R&D end dates and study feasibility* |
| **10.0** | **DATA** |  |
| 10.1 | Data collection (Case Report Form (CRF)/eCRF) tools ready for use? | *Specify type, version, and date*  *Document if reviewed by JRMO (if lone investigator)* |
| 10.2 | Data collection (CRF/eCRF) tools signed by CI and statistician? |  |
| 10.3 | Case report forms reviewed by monitor (lone-Investigator trials only) |  |
| 10.4 | Database to be used? | *Specify type, version, and date* |
| 10.5 | Database ready and validation paperwork present? | *JRMO IT to confirm in writing* |
| 10.6 | Discussed frequency of data entry and data lock, end of trial. |  |
| **11.0** | **TRIAL COMMITTEES** |  |
| 11.1 | Trial committees confirmed  Charter drafted and agreed by Chair (minimum) and where possible whole committee | *List committees* |
| 11.2 | Members list confirmed in writing | *Frequency of meetings discussed and logged by GCP team* |
| 11.3 | CVs (signed and dated) and Conflict of interest forms collected | *Pending first meeting is acceptable* |
| **12.0** | **LABORATORIES** |  |
| 12.1 | Details of laboratories and collection areas: |  |
| 12.2 | Sample and laboratory collection SOPs in place and discussed? |  |
| 12.3 | Individual Laboratory approval received | *Central facilities- Laboratory manager and Head of lab* |
| 12.4 | Relevant material’s transportation/transport discussed | *Between locations between sites and between NHS/non-NHS sites*  *Detail courier to be used* |
| 12.5 | 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.* |
| 12.6 | End of trial destruction/banking of tissue discussed |  |
| **13.0** | **Other Central facilities** | *Consider central imaging review or collection, etc.* |
| 13.1 | List all central facilities |  |
| 13.2 | 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.* |
| **14.0** | **EQUIPMENT** |  |
| 14.1 | List study specific equipment to be provided to sites | *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.* |
| 14.2 | Equipment storage location and custodian identified |  |
| 14.3 | MHRA approval (where relevant) |  |
| 14.4 | Confirmation of equipment indemnity | *Master Indemnity Agreement (MIA) where on loan or gifted* |
| 14.5 | Study specific SOP in place |  |
| 14.6 | Frequency of equipment maintenance recorded by monitors |  |
| 14.7 | Approved by sponsor’s Clinical Physics representative? |  |

| Summary of actions needed | | Person delegated |
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