**Clinical Investigations: Guidance for GCP and Governance section staff**

It is mandatory to organise an official kick-off meeting for all Clinical Investigations of Medical Devices, and any other clinical trials of medical devices that will be regulated by the Medicines and Healthcare products Regulatory Agency (MHRA). All actions from the kick-off meeting must be completed before *Sponsorship with Conditions* is issued.

The aims of the meeting are:

* To ensure that all key staff within the sponsor organisation have a full understanding of the design, purpose, and requirements of the Clinical Investigation.
* To identify all third parties that will be contracted to successfully complete the Clinical Investigation so that they can be assessed and contracted.
* To ensure that the actions required for *Sponsorship with Conditions* are identified and completed.
* To identify and discuss any additional details of the Clinical Investigation which may not be clear from the sponsorship application.

It is mandatory for the following staff members to attend the kick-off meeting. The meeting must not be held without all being present:

* Chief Investigator (CI)
* Trial coordinator / Trial manager
* JRMO GCP & Governance manager
* JRMO Clinical Trial Monitor
* JRMO Research Management and Governance Officer (RMGO)
* JRMO Contract Officer
* Representative from the sponsor’s clinical physics department

It is also strongly recommended that the representative of the manufacturer of the investigational device attends the meeting where appropriate.

Additional members of the study team may be invited to attend.

As general guidance:

* A 90-minute meeting slot should be allocated.
* The meeting must not be held until a valid submission has been received, and ideally not until the initial feedback has been provided to the study team.
* Minutes or notes and actions must be documented and agreed and saved as part of study set-up documentation.
* Review revised documents and the individual role set-up checklist (associated document 9). Work with the CI and team to ensure that a GCP compliant protocol has been achieved and a consensus is reached.
* Ensure that the CI is aware of study set-up SOPs including: SOP 45 Study Specific File Essential Documentation and , SOP 46 Site selection, site initiation & site activation, SOP 47 Trial Committees, and associated documents so that relevant study documents are under development to avoid any delays with the ‘Sponsorship with conditions process.

**Kick-off meeting agenda template**

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| **Agenda Points** | **Suggested notes** | **Lead** |
| Introductions |  | GCP & Governance Manager/RMGO |
| Summary of status of study  | * Valid submission received/Initial feedback sent.
 | RMGO |
| CI briefly describe Clinical Investigation  | * RMGO to request the CI to prepare for this. It’s useful to hear summary of study and it is appropriate to ask for a lay explanation so that it is understandable to all.
 | CI |
| Resources and Support | * Sponsor- Who is the CI’s substantive employer?
* Confirm that the CI has capacity to run the Investigation.
* Discuss CI’s experience with Clinical Investigations, CTIMPs, and other clinical research.
* Coordinator support confirmed? Include National Coordinating Centres if international.
* Trial statistician confirmed?
* Sites, nations and PICs?
* NIHR portfolio status
* Funding sources
* Funding award agreement(s)
* Funding letters for Portfolio Adoption process (stating amount and duration to cover project)
* Protocol Peer review (See SOP 14 Peer Review)
* Training requirements, including ISO14155 GCP training.
 | RMGO |
| Recruitment & participant population discussed, including feasibility of meeting targets | * Site selection and activation procedures.
* Patient pathways
* Conflicting studies
* Reporting first patient consented
* Reporting portfolio study figures monthly to the JRMO
 | RMGO |
| Documents | * Status of document set
* Delegation of responsibilities
* Risk Assessment
* Trial Master File
* Version control requirements
 | RMGO & GCP & Governance Manager |
| Investigational Device  | Including but not limited to:* Source of Investigational Device
* Clinical Physics Assessment
* Supply to sites
* Installation requirements
* Electrical safety testing
* Calibration & maintenance
* Sterilisation
* Device accountability
* Incorporated software
* Disposal or return
* Manufacturer responsibilities
* Clinical physics agreement to proceed
 | GCP & Governance Manager/Clinical Physics Representative |
| Vendors & Contracts  | Including but not limited to:* Identify all vendors, service providers and Internal Queen Mary/ Barts Health departments.
* Site agreements (are we providing any consumables?
* Investigational device supply agreement and collaboration agreement with the device manufacturer.
* Lab Service Level Agreement(s)
* Material Transfer Agreement(s) – Any data or tissue being sent any location other research sites?
* Statistician
* International Agreements
* Translators
* Insurance – additional premiums required?
 | Contract Officer |
| Data Management  | * Database
* Provider
* Data management plan
 | GCP &Governance Manager |
| Safety Reporting | * ISO14155 Safety Reporting Requirements
* Safety reporting to manufacturer.
* Responsibility for safety reporting to the MHRA
 | GCP &Governance Manager |
| Monitoring arrangements  | * Clinical trial monitor(s) introduced.
* Monitoring plan agreed
 | Clinical Trial Monitor/ GCP & Governance Manager |
| Quality Assurance/Compliance/Study Specific SOPs | * Trial unit/group specific SOPs discussed and relation to JRMO QMS?
 | GCP &Governance Manager |
| AOB  | * Feedback to discuss
 | RMGO / GCP & Governance Manager |
| Close | * Summary and plan of action
 | RMGO/GCP & Governance Manager |