Joint Research Management Office (JRMO)

Early engagement meeting: Clarification Tool

This tool can be used by either the assigned governance officer or assigned Good Clinical Practice (GCP) manager and Costing & Contract Manager at the initial planning stages of a Medicines and Healthcare products Regulatory Agency (MHRA) Regulated Clinical Investigation.

Text in Italics are items to be considered and not an exhaustive list; these can be removed. A summary should be inserted into each section.

Sponsor Who is the Chief Investigator's (CI) substantive employer? UK or International
CI Experience As CI on: Non-Commercial MHRA Regulated study Commercial MHRA Regulated study Or as Principal Investigator on: Non-Commercial MHRA Regulated study Commercial MHRA Regulated study Or as co-investigator Note whether the experience in is research studies, interventional device studies, other interventional studies, CTIMPS, ATIMP or Clinical investigations (N.B Locum & Emeritus Professor cannot be Investigators - see SOP 11a for guidance)
Sites In the UK How many Countries Total (See SOP 21 for Sponsorship, management, and oversight of international-only research: Competent Authority Regulated studies and interventional research for guidance on National Coordinating Centres (NCC))
Investigational Device Manufacturer Who is the manufacturer of the Investigational Device? Have they agreed to be named on the Clinical Investigation Plan and IRAS & MHRA application Form? Which documents will the manufacturer be providing for the regulatory application? What will they be responsible for (e.g. device maintenance, calibration, safety reporting)? Do they have experience? Do they need to be vendor assessed? Clarify Indemnity/ insurance situation
Service Providers • *Site agreements (are we providing any consumables? E.g., tissue kits, equipment, device / funding for collaborators to the sites)?* • *Are you planning to recruit from any other sites? (Site or Participant Identification Centres (PIC))* • *Which areas in Barts Health/Queen Mary will you be using for clinical and non-clinical interventions?* • *Contract Research Organisation (CRO)?*

- *Will they be using Clinical Research Coordinator (CRC) or another unit if a lone investigator?*
- *Laboratory Service Level Agreement(s)- to be used in a MHRA regulated study the lab must be fully GCP compliant (see SOP 43 Laboratories)*
- *Material Transfer Agreement(s) – Any data or tissue being sent any location other research sites?*
- *Database Provider?*
- *Statistician*
- *Unblinding service*
- *Randomisation service*
- *International Agreements*
- *Translators*
- *Importers/ Exporters*
- *Equipment*
- *Is there any equipment or device (in addition to the device being tested) on loan or being gifted by from manufacturer? Is it on the Master Indemnity Agreement (MIA) (indemnifying the kit)?*

Risk Assessment (See SOP 23 Risk Assessments)
Note any key elements to be considered when the Risk assessment is completed

Funding

- *Funding award agreement(s)*
- *Funding letters for Portfolio Adoption process (stating amount and duration to cover project)*

Protocol Scientific Peer review (See SOP 14 Peer Review)

Databases, Systems and Management (See SOP 38 a-d for SOP on these topics)

Investigational Device Management (ideally clinical physics would be present for an early engagement meeting)

Give clinical physics contact.

What are the calibration/ maintenance/ sterilisation requirements of the device?
How will the security of the device be managed? If the device incorporates software, then this includes cyber security.
What will happen to the devices at the end of the study?

Safety Report (see SOP series 26 Pharmacovigilance)

Monitoring (see SOP 28 Monitoring)

Quality Assurance/Compliance/Study Specific SOPs?

See JRMO SOPs and SOP 11b AD 1 Guidance for GCP and Governance section staff Appendix A
IRAS application - progress and JRMO submission