MAC Clinical Research

JOB DESCRIPTION

NAME:

JOB TITLE: EPU Study Co-ordinator 1

REPORTS TO: EPU Senior Study Co-ordinator/Head of Early Phase Unit

FOCUS OF THE JOB: To objectively assess and apply project management knowledge to ensure that the clinical phase of the project is completed in accordance with the scope, quality, timelines and cost of the contract.
To effectively coordinate 1-2 concurrent clinical research trials

KEY SKILLS, KNOWLEDGE AND QUALIFICATIONS REQUIRED:

- RGN / RMN or
- BSc Nursing / Biomedical or
- BSc in a scientific field / relevant clinical trial experience.
- In lieu of Bachelor's degree a minimum of 5 years clinical research experience.
- 1 year minimum experience within the field of clinical trials.

RESPONSIBILITIES (including staff):

1. Study Set-up in the Clinical Unit
    - Review the study protocol and ensure review within the wider clinical team.
    - Assist the PM in creation/review of the PIS and VICF
    - Assist in preparation and completion of the risk management plan
    - Ensure study specific clinical documents are prepared and where appropriate review.
    - Ensure any study specific equipment is available, calibrated as required and that training is provided if necessary.
    - Review the eCRF and source documents and ensure review by the wider team.
    - Create delegation log checklist and manage delegation log
    - Creation, maintenance and ongoing QC of hard copy of the Investigator Site File.
    - Host SIV and organise Study Specific Protocol Training
2. Ensure the smooth progress of studies in Clinical Phase
    - Maintain an awareness of recruitment issues and deadlines and promote and assist in recruitment activities where required.
    - Create and maintain the Screening/Enrolment Log
    - Support and oversee clinical activity alongside the Lead Study Nurse.
    - Generate and QC clinical procedure sheets.
    - Ensure dose escalation data is produced in accordance with the regulations and SOPs and ensure QC of the Interim Safety Report is performed.

- Manage protocol deviations
- Communicate updates to appropriate clinical departments e.g PM and client (where appropriate) – recruitment and study progress, sample shipment.
- Participate in internal and external clinical and project audits.
- Monitor and appropriately report AEs/SAEs
- Ensure appropriate documentation of Pharmacy requirements on study.

3. Communication and Teleconferences
    - Participate in project calls and Sponsor TC where appropriate
    - Participate in clinical team meetings
    - Ensure biological samples are shipped according to schedule.
4. Clinical Data Monitoring
    - Assist in the QC of clinical data from screening through to post study medical for all volunteers at appropriate timepoints. Ensure that all subjects have a valid screen release prior to check-in.
    - Liaise with clinical staff to ensure resolution of data queries prior to sponsor monitor visits, to ensure clean data is provided to the monitor.
    - Host monitoring visits, be available to resolve monitoring queries and ensure all documents are available for the monitors.
    - Ensure all data is uploaded into the eCRF and queries answered within timelines.
5. Post Clinical Phase activities
    - Ensure all data is finalised in eCRF ready for PI signoff according to timelines.
    - Ensure all biological samples are shipped off site according to the schedule.
    - Return of any study specific equipment that has been used in the study.
    - Host close-out visit and prepare the documents for archiving.
6. Other
    - Compliance with MAC health and Safety policy
    - Compliance with MAC policy on equality and diversity
    - To maintain professional qualifications required for the role, including continuous personal development
    - To work to the requirements of SI 2004 no 1031 and amendments thereof, which includes Good Clinical Practice
    - To work according to MAC SOPs, guidelines and policies
    - To work according to current data protection standards and practice good information management. Maintenance of strict confidentiality of patient and business related data.
    - To maintain a high level of initiative and personal responsibility, liaising appropriately with team members and managers to ensure your job role is efficiently carried out
    - To support the aims of MAC and to represent MAC appropriately in a professional way to all our customers

PHYSICAL, WORK ENVIRONMENT, TRAVEL DEMANDS:

- Potentially long periods standing.
- Dealing with bodily fluids.
- Long periods looking at a computer screen.
- Meeting deadlines and working within strict timelines.
- Ability to travel between sites if required.
- Ability to travel to national / international meetings.

LIMITATIONS AND DISCLAIMER

The above job description is meant to describe the general nature and level of work being performed; it is not intended to be construed as an exhaustive list of all responsibilities, duties and skills required for the position.

Employees signature……. Date…….

Head of Department signature…….. Date…….