ROLE TITLE: **CLINICAL STUDY/PROJECT MANAGER**

Valid from January 2021

LOCATION: Head Office-Welwyn Garden City, Hertfordshire

REPORTS TO: HEAD OF CLINICAL OPERATIONS

1. PURPOSE OF ROLE

To aid in the development of new drug and device therapies by supporting the set-up, approvals process and co-ordination of assigned studies in accordance with PHARMExcel Standard Operating Procedures (SOPs) and policies, International Conference on Harmonisation (ICH) and Good Clinical Practice (GCP) guidelines, ISO 14155 (GCP medical devices) and applicable EU/US clinical trials legislation/guidance.

To work flexibly to ensure that assigned study objectives and deadlines are met.

To organise workload and cope with conflicting demands on time, whilst prioritising workload accordingly.

To adhere to PHARMExcel information governance and confidentiality policies.

Will be required to attend a Good Clinical Practice (GCP) course/undertake GCP training within 3 months of starting if he/she has not already done so.

2. KEY AREAS OF RESPONSIBILITY

You will be responsible and accountable to ensure effective cross-functional teamwork to secure the successful completion of your trials by:

Project Management;

- Proactively engaging in risk management activities to ensure key milestones and project deliverables are met according to both PHARMExcel and client requirements.
- You will be accountable to meet the financial performance targets for your assigned studies, responsible for performing forecasting, revenue recognition, maintaining profit margin and to proactively identify out of scope activities and execute necessary work scope change orders.
- Establishing relationships with client teams which result in client satisfaction, operational excellence and thereby increase potential for repeat business. You will also be responsible for appropriate issue escalation
- Preparing regular communications/reports to client/sponsor/Investigation sites
- Organising and coordinate meetings and events as required on behalf of client/sponsor, circulating agendas and other information in advance and writing and disseminating minutes
- Managing workload priorities ensuring the more urgent and important tasks are completed first within required timescales

Study Management;

- Developing the clinical study protocol and ensure input, review and finalisation occurs within budget and timelines.
- Overseeing and/or creating all relevant operational documents required for the smooth running of the study, including project, monitoring, communication, quality and safety management plans according to PHARMExcel's SOPs
- Completion/oversight of Ethics Committee (EC) and Competent Authority (CA) clinical trial applications in accordance with PHARMExcel's SOPs
- Completion/oversight of applicable local submissions in accordance with PHARMExcel's SOPs
- Conducting study Quality Control (QC) activities throughout the study lifecycle to ensure study processes are in line and compliant with regulations and in accordance with PHARMExcel's SOPs/WIs
- Working alongside CTAs to ensure assigned projects have an appropriate clinical trial file, including Trial Master Files (TMF), In-House Investigator Site Files (hISFs), Investigator Site Files (ISFs), Pharmacy Files (PF), Laboratory Files, and in-house electronic files and are audit ready
- Liaising with CTAs to ensure distribution of essential documents such as protocols, investigator brochures, and clinical study reports to investigational sites for assigned projects

- Ensuring sufficient stocks of study related consumables at investigational sites, creating and maintaining trackers where required, for availability of stock for assigned projects
- Supporting monitoring activities for assigned projects by assisting the study CRA in preparation and follow up tasks as well as accompanying the study CRA on site visits as required
- Supporting study close out activities for assigned projects, including preparation of study documentation for archive, and collaborate with the site archivist to organise off-site archiving in accordance with applicable regulations

Quality Assurance

- Initiating and driving improvements to enhance efficiency and quality.
- Supporting with the preparation of new SOPs and documents as required.
- Assisting Quality Assurance function in supporting process improvement across the organisation

General duties

- Complete time-sheets for each project assigned
- Encourage a team culture that fits within PHARMExcel's work ethos creating a team environment which supports process improvement, innovation and personal accountability
- Undertake any other duties commensurate with the position

NB. The role description is a reflection of the current position and may change emphasis or detail in the light of subsequent organisation developments, in consultation with the post holder.

3. INTERFACES AND INTERDEPENDENCIES

Internal

- Report to Head of Clinical Operations
- Work alongside other clinical staff providing cross over of work where required
- Support CRAs and provide necessary documentation for monitoring visits
- Support CTAs and provide all necessary documentation for TMFs
- Liaise with Data Management to ensure DM processes are adhered to for the study
- Work with Quality Assurance function to implement quality improvements across the organisation

External

- Client/Sponsor
- Clinical Research Sites
- ECs/IRBs
- Regulatory Authorities
- Research funding organisations

4. PERSON SPECIFICATION

Knowledge and skills

Essentials

- 1-2+ years demonstrated clinical research experience in a pharmaceutical company/CRO/CTU (i.e. study coordinator/study manager/project manager)
- Working knowledge of ICH Guidelines and GCP including international regulatory requirements for the conduct of clinical development programs.
- Broad knowledge of drug development process and client needs.
- Strong organisational and time management skills
- Excellent interpersonal skills both written and verbal. Ability to confidently communicate with an array of internal and external contacts
- Financial awareness and ability to actively utilize financial tracking systems
- Scrupulous attention to detail
- Ability to work as part of a team and independently in an enthusiastic, pro-active fashion
- Willingness to travel on an occasional basis
- Extensive knowledge of Microsoft based packages and database applications such as Access and Excel

Desirables

- Experience of early phase work
- Familiarity with ISO 14155 and the Medical Devices Directives (as amended)

Values and behaviours

- Professional
- Self-motivated
- Organised, ability to multi-task, ability to motivate and organise others
- Flexible and proactive approach with a “can do” attitude
- Delivers high quality work
- Willingness to accept and make changes in a fast paced environment
- Able to work independently whilst also being a strong ‘team player’

5. IMPACT

- Will quickly get to know the organisation ethos and study workload
- Will build good working relationships with all team members
- Will balance support across a number of studies at different stages ensuring studies have the appropriate level of support at all times
- Will work independently (but with some support and oversight) to prioritise workload under pressure and work to changing business needs
- Will strive to improve functional and study team ways of working and share best practice across the clinical team
- Will have confidence in own abilities and know when to be assertive and diplomatic
- Will work to challenge the status quo and improve on current best practice