ROLE TITLE: **CLINICAL RESEARCH ASSOCIATE II**

Valid from Dec 2020

LOCATION: ***Home/Office based**

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.

Act as PHARMExcel direct contact with sites and use judgment to assess and ensure overall integrity of study implementation, as well as adherence to study protocols. Build strong working relationships with investigators and site staff. Accountable for monitoring activities, including: Arranging on-site visits and logistics; Establishment of site recruitment plans in collaboration with site staff during Qualification Visit (QV); Monitoring completeness and quality of regulatory documentation; Performing source data verification (SDV), data collection and drug/device accountability activities; Monitoring patient safety on-site and addressing any violations in a timely manner.

You will also be involved in supporting the Clinical Study/Project Managers to undertake Ethics and Regulatory submissions as required.

To d take responsibility and accountability to ensure that assigned monitoring objectives and deadlines are met.

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.

*During the probation period (3 months) you will be required to work at the PHARMExcel Head Office, located in Welwyn Garden City, Hertfordshire. After probation, you will be required to travel to the PHARMExcel Head Office, for a minimum of 2 times per month. Days to be agreed with line manager and dependent on project/ travel commitments.

2. Key Areas of Responsibility

Planning and delivery

- Feeding into the development of trial protocols with regard to monitoring requirements
- Feeding into study planning and logistics with Clinical Study/Project Manager(s) with regards to study visits and scheduling
- Writing monitoring plans in accordance with sponsor's risk of trial
- Ensuring monitoring activities are undertaken in accordance with overall project timelines, in accordance with internal procedure and applicable GxP regualtions and guidelines.

Specific responsibilities for which you will be accountable for include:

- **Site Selection**
  - Identifying and assessing the suitability of facilities to be used at the clinical trial site
  - Identifying/selecting investigators (where required) who will be responsible for the conduct of the trial at the trial site
  - Prepare/review all associated documents related to these activities
- **Site Set-up**
  - Setting up the trial sites, which includes ensuring each centre has the trial materials, including the trial drug/device/intervention
  - Assisting with Ethics and Regulatory submissions and ensuring applicable approvals obtained
  - Review site TMF with CTA
- **Site Initiation/training**
  - Prepare/review all associated site documents related to these activities
  - Deliver study specific related training to site including SIV meeting
  - Training site staff to trial-specific industry standards
- **Site Management/Monitoring to Close Out**
  - Liaising with Investigators and site teams on conducting the trial
  - Manage the progress of assigned projects ensuring all regulatory documents are up to date
  - Facilitate case report form (CRF) completion and submission, data query generation and resolution by site – including reviewing data collection forms to ensure in line with trial protocol; Verifying that data entered on to the CRFs is consistent with souce documents, (SDV)
  - Create and maintain appropriate documentation regarding site management, monitoring visit findings and action plans by submitting regular visit reports, generating follow-up letters and other required documents
  - Work with sites during the study to support and track subject recruitment to ensure targets are met
  - Monitoring the trial throughout its duration, which involves visiting the trial sites on a regular basis – as per study monitoring plan

- Escalate study quality issues to Clinical Study/Project Manager as appropriate
- Escalate serious breaches of the protocol and/or GCP to the Clinical Study/Project Manager
- Ensuring all unused trial supplies are accounted for
- Closing down trial sites on completion of the trial
- Archiving study documentation and correspondence

- **General Day to day responsibilities**
  - Manage workload priorities ensuring the more urgent and important tasks are completed first within required timescales
  - Complete time-sheets for each project assigned.
  - Work with the Head of Clinical Operations and Senior Clinical Study/Project Manager and support process improvements related to role and/or cross-functional teams, including generation of controlled forms, SOPs and Guidance Documents
  - Encourage a team culture that fits within PHARMExcel work ethos creating a team environment which supports process improvement, innovation and personal accountability
  - Undertake travel as required to fulfil post (this may involve international travel)
  - 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.

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3. INTERFACES AND INTERDEPENDENCIES

Internal

- Report to Head of Clinical Operations and support business activities as required
- Work alongside all team members providing cross over of work where required
- Liaise with Data Management vendors to ensure DM processes are adhered to for the study

External

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

4. PERSON SPECIFICATION

Knowledge and skills

Essentials

- Demonstrated experience (2-3years+) of monitoring multiple, multi centre Interventional clinical trials at a CRA-I level (or equivalent)
- Previous experience in undertaking ethics and/or regulatory submissions
- 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.
- Scrupulous attention to detail and ability to meet deadlines
- Ability to work as part of a team and independently in an enthusiastic, pro-active fashion
- Willingness to travel as required for monitoring projects assigned (may include intrnational travel)
- Educated to degree level or equivalent (preferably in a science related subject)
- Experience of collecting, handling and tracking data
- Extensive knowledge of Microsoft based packages and database applications such as Access and Excel
- Detailed knowledge of ICH/GCP guidelines, EU Clinical Trials Directives (as amended) and FDA regulations and guidelines (as amended)

Desirables

- Early phase/ongology experience
- Familiarity with ISO 14155 and the Medical Devices Directives

Values and behaviours

- Demonstrates honesty and integrity
- 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’
- Passionate about research

5. IMPACT

- Will quickly get to know the organisation ethos and study workload
- Will build good working relationships with all team members
- Will work independently 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 coordinators
- Will have confidence in own abilities and know when to be assertive and diplomatic
- Develop junior team members to excel in their role and achieve their maximum potential
- Will work to challenge the status quo and improve on current best practice