ROLE TITLE: **ENTRY LEVEL-CLINICAL TRIAL ADMINISTRATOR**

Valid from January 2020

LOCATION: **Head Office-Welwyn Garden City, Hertfordshire**

REPORTS TO: **SENIOR CTA**

1. PURPOSE OF ROLE

To aid in the development of new drug and device therapies by providing specialist, administrative support to our Clinical Trial Management and Study/Project Management teams. You will maintain and track clinical study documentation, coordinate study materials, and collate relevant study information in accordance with PHARMExcel's 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 support/assist the CTA team to organise workload and ensure study files are audit ready.

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.

2. KEY AREAS OF RESPONSIBILITY

Induction and Training

Understand and apply knowledge regarding;

- the drug and medical devices development cycle and how this applies to the clinical research environment
- the various roles within the pharmaceutical and device industries
- clinical /medical terminology used within research
- the role of a Contract Research Organisation (CRO)
- the role of a CTA
- clinical trial essential document management (trial master files and site files)
- regulations supporting clinical trials (ICH -GCP, UK/EU regulations and US regulatory framework)

Planning and Delivery -Support CTAs to;

- Ensure Trial Master File (TMF) set up and maintenance for all projects in accordance with PHARMExcel procedures
- Ensure In-House Investigator Site File (hISF), set up and maintenance in accordance with PHARMExcel procedures
- Ensure Investigator site file set up and distribution in accordance with PHARMExcel procedures
- Ensure all final study documents are scanned and uploaded to SharePoint to ensure remote access for staff
- Undertake Quality Checking (QC) and oversight of in house files with sCTA/CTAs
- Undertake Quality Checking (QC) and reconciliation between paper and electronic files with sCTA/CTAs
- Undertake document archiving in accordance with PHARMExcel procedures and project requirements/client contract
- Liaise with sCTA/CTAs to ensure distribution of essential documents such as protocols, investigator brochures, and clinical study reports to investigational sites for assigned projects
- Attend project meetings and generate meeting minutes
- Manage workload priorities ensuring the more urgent and important tasks are completed first within required timescales
- 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 Senior CTA
- Liaise on day to day basis with Senior CTA/CTAs to ensure the document management requirements of all projects are met
- Support other CTAs and the Clinical Research Associate (s) and provide necessary documentation for monitoring visits
- Support Study Manager/Project Managers with any trial administrative requirements

External

- Client/Sponsor
- Clinical Research Sites

4. PERSON SPECIFICATION

Knowledge and skills

Essentials

- Bachelor's degree in life sciences
- 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
- Ability to work as part of a team and independently in an enthusiastic, pro-active fashion
- Willingness to travel on an occasional basis
- Experience of collecting, handling and tracking data
- Working knowledge of Microsoft based packages and database applications such as Access and Excel

Desirables

- Knowledge of medical terminology/clinical research environment

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 assist to balance CTA support across all projects at different stages ensuring studies have the appropriate level of support at all times
- Will work under guidance to prioritise workload and work to changing business needs
- Will strive to improve functional and study team ways of working and share best practice
- Will have confidence in own abilities and know when to be assertive and diplomatic