Job Description

Job Title: Clinical Trials Support Officer (CTSO)

Reports to: Research Nurse Manager

Job Summary

The CTSO post-holder will assist Panthera clinical staff with the coordination of blood sampling and processing for active clinical trials at the research centre.

This includes maintaining effective systems for stock control of clinical trial kits, courier management as well as temperature monitoring of equipment.

The post holder will be responsible for maintaining equipment records, ensuring there are valid calibration certificates in place.

The post holder will be responsible for ensuring that the clinical team have the correct kits in place for the next clinical day.

The post holder will be responsible for ensuring that the clinical rooms are stocked and ready for the next clinical day.

The post-holder will be responsible for ensuring the trial data is entered into the sponsors electronic system meeting the sponsors expectations.
The post holder to communicate trends and repeated system flags to the Site Compliance Specialist.

The post holder will work closely with the Panthera Research Practitioners (RP), to support screening processes and preparation for start-up of clinical trials.

The post holder will be required to work across local Panthera sites as required.

Personal Attributes

The post-holder should have excellent interpersonal skills, energy, pro-active drive and enthusiasm for the role, to ensure that high quality clinical research is delivered according to agreed targets.

Key Responsibilities

Communication and Relationships

- Building key relationships with stakeholders, colleagues, clients, monitors, CRA's and patients.
- Effective communication with the UK Panthera site teams, including management of emails.
- Assisting RP's with preparation for clinical visits
- Supporting the team in the set up and management of clinical trials

Information & Data Quality/Collection

- Responsible for complex data collection, transcribing information into case report forms in accordance with Good Clinical Practice
- Ensuring accuracy and high quality of data input in to Panthera systems
- Ensuring patient notes are always complete and up to date
- Take personal responsibility for safeguarding and ensuring the quality of information for patients, clients and vendors
- Responding promptly to requests for information to support the Panthera team as required.
- Contributing to communication materials including activity reports, presentations, Panthera promotional materials, such as posters and company newsletters.

Clinical Support

- Liaising with external lab vendors and Sponsors to ensure safe and timely transfer of samples as required and in accordance with IATA guidelines.
- Supporting research practitioners with the processing of tissue samples for clinical trials as per individual trial protocol.
- Taking of blood samples, managing patient expectations and care.
- Performing other procedures in accordance with the protocol requirements and as appropriately trained, including but not limited to height, weight, BMI calculation, blood pressure, oximetry, fibroscan.
- Managing stock control of clinical trials consumables.
- Maintaining clear and accurate records pertaining to samples and stock for clinical trials.
- Working with clinical delivery team to manage own workload across a wide range of specialities.
- Meeting regularly with the research teams to ensure all required parties are aware of the current status of on-going projects.
- Monitoring of temperature controls in the lab, including Fridges and Freezers.
- Completion of monitoring logs.

Quality Management Systems and Processes

- The post-holder must consider and comply with all Panthera policies, procedures and initiatives including, but not limited to, quality standards, compliance and auditing requirements, confidentiality and information security.
- Reporting quality issues in accordance with Panthera SOP's.
- Adhering to policies standard operating procedures, required by the Sponsor in the conduct of clinical trials.

The post holder will always operate with integrity and professionalism, complying with regulatory requirements in accordance with the following;

- ICH-GCP
- IATA guidelines
- Annex 13 – GMP
- Health and Safety regulations
- All Panthera policies and procedures in particular Infection Control and reporting of quality issues
- Data Protection Act 2018/ GDPR 2018
- Ant-bribery and Corruption Act 2010
- Health & safety at work Act 1974
- Professional codes of conduct

Training

- Attend all mandatory training applicable to this post within the required timescales.
- Seek opportunities to develop own skills.
- Adapt to any changes in the requirements of new clinical trials, or amendments to the protocol on trials that are ongoing.
- Attend any Sponsor or company training events as applicable.

Personal Development

- Actively participating in the annual Personal Development Review (PDR) process.
- Aspiration to work towards Project Management and support the Project Lead on clinical trials as required.
- Able to work on own initiative without supervision, managing own workload and working independently as well as part of the Panthera team.
- Contribute to positive working behaviours and attitude.
- Commitment and passion to the development and delivery of clinical research.
- Take responsibility for ensuring targets and deadlines are met and an exemplar service is provided.

Promoting Equality and Reducing Inequalities

- To understand and uphold organisational policies and principles on the everyday promotion of equality, diversity and inclusion.
- To create an inclusive working environment in which a variety of ideas, experiences and practice are valued, and where differences are respected and celebrated for the benefit of ourselves, Panthera and the communities we serve.

The range of duties and responsibilities outlined above are indicative only and are intended to give a broad flavour of the range and type of duties that will be allocated. They are subject to modification in the light of changing service demands and the development requirements of the post holder.

Job Review

This job description will be reviewed periodically to take into account changes and developments in service requirements. Any changes will be discussed fully with the post holder.

Post holder's Signature: _____

Site Manager Signature:_____

Date:_____

Person Specification

Description	Essential	Desirable	Assessment
Education/ Qualifications	• NVQ Level 3 or equivalent	Health related qualification	Application/Interview
Knowledge & Experience	• Ability to take detailed and accurate notes, transposing and recording information • Processing complex information (data entry) • Knowledge and accomplishment in the processing of blood samples • Communication at different levels within an organisation	• Previous experience of clinical trials • Experience of processing blood and urine samples • Recording and understanding of procedural results	Application/Interview
Skills and Abilities	• Able to demonstrate attention to detail • Able to communicate effectively and politely through various means • Face to face communication essential • Able to balance competing priorities • Able to demonstrate active listening • Able to confidently promote research to patients and prospective volunteers	• Able to demonstrate competency in the following area's; • Venepuncture • ECG • Blood Pressure • Height/Weight/BMI • Oximetry • Spirometry • Breath tests	Application/Interview
Attitudes and Qualities	• Pro-active mind set • Motivated and keen to learn new skills • Flexible approach • Committed to improving quality through research • Able to demonstrate commercial awareness		Application/Interview