Job Description

Department: Clinical Operations
Job Title: Clinical Trial Specialist
Reports to: Senior Director / Designee, Clinical Operations

Primary Objective of Position

The Clinical Trial Specialist (CTS) is responsible for providing operational support for the day-to-day execution of clinical trials, following established SOPs, GCP and applicable regulatory requirements in the execution of all activities; proactively identifying and resolving operational project issues; and participating in process improvement initiatives as required.

Major Duties/Responsibilities

- Ensures timely and accurate study-related communication to clinical personnel (eg, internal and external study teams, consultants and investigative site personnel); prepares and disseminates clinical trial correspondence, newsletters, and IND safety letters (working with project clinician); and assists with the creation of study-specific manuals, tools, and templates.
- Participates in selection and management/oversight of external vendors and develops vendor specifications; reviews vendor reports, budgets, and metrics; acts as liaison between vendors and sites (eg, assists sites with laboratory sample queries).
- Coordinates specified clinical trial meetings (eg, investigator meetings, study team meetings, CRA and CRO meetings) by arranging logistics, preparing necessary materials and recording and distributing minutes.
- Sets up, tracks, collects and maintains audit-ready clinical trial documentation and study status in an electronic system; manages and tracks regulatory/IRB/IEC documentation, IND safety letter distribution, confidentiality disclosure agreements, and other clinical trial documents; performs initial QC of electronic data feeds; generates, reviews and distributes reports; assists with quality assurance audits and resolution of audit findings.
- Participates in study design and execution by contributing operational experience and expertise: provides input into protocol, ICF, CRF design, monitoring conventions, edit checks and vendor specifications; assists with study or site feasibility process; posts and maintains study-related information on external websites when applicable.
- Ensures that necessary study supplies are available as per study timelines: sources clinical trial supplies through external vendors (eg, case report forms, study manuals, lab kits); manages, reviews and tracks drug shipment, destruction, and return; coordinates internal lab sample supply set-up and shipment.
- Maintains ongoing communication with site staff to resolve issues (eg, data queries, study management), support the staff, oversee the efficient conduct of the trial, and ensure continued compliance.
- May also be responsible for acting as a central point of communication between Puma and investigative sites for all assigned clinical trial-related activities to assure trials are conducted on time and budget, while fully compliant with ICH GCP and the SOPs in effect. In this role, the CTS may be responsible for:
    - Conducting on-site visits consistent with the applicable Clinical Monitoring Plan and SOPs for site qualification, site initiation, routine monitoring, site close-out and other site visits (eg, booster), as requested
    - Overseeing site recruitment, implementing appropriate contingency plans, as needed
    - Assessing site performance and conducting training/re-training when necessary to ensure site compliance with the protocol, applicable regulations and Puma expectations
    - Writing confirmation letters, follow-up letters and site visit reports that conform with guidelines and timelines stated in the applicable Clinical Monitoring Plan and SOPs

- Performs other tasks, as assigned by the manager/designee to promote the efficient conduct of the trial.

Skills & Abilities

- Clear and timely communication, both written and verbal
- Ability to handle a moderate volume of tasks within an established timeframe
- Strong organizational skills and ability to prioritize
- Ability to build relationships within the team, across departments, and with external contacts (eg, vendors, site staff)
- Proactively identify and resolve/escalate project-related operational issues
- Ability to work independently on routine assignments, or under supervision on new assignments
- Familiarity with word processing, spreadsheet and document management systems

Physical Demands

The physical demands of the office are normally associated with extended amounts of time sitting and using office equipment, including a computer, keyboard and mouse, which can cause muscle strain. While performing the duties of this job, the employee is frequently required to stand, walk and sit. Periodic light lifting of supplies and materials may apply.

Travel (including air) may be required up to 75% for those conducting field monitoring. This may include carrying a laptop, lifting luggage and possibly long flight times.

Education & Professional Experience

Required:

- Bachelor's degree or equivalent combination of education/experience, preferably in science or a health-related field
- Strong understanding of GCP, ICH and knowledge of regulatory requirements

Preferred:

- One year of clinical research experience or health-related experience (eg, study coordinator, data management, nursing)
- Completion of Puma Field Monitoring Course or equivalent, as required for field monitoring activities
- Oncology experience
- Global trial experience

Approvals

Employee

Signature_____ Date_____

Printed Name_____ Title_____

Supervisor

Signature_____ Date_____

Printed Name_____ Title_____