Job Description

Department: Clinical Operations
Job Title: Clinical Research Associate
Reports to: Director / Designee, Clinical Operations

Primary Objective of Position

The Clinical Research Associate (CRA) is responsible for acting as a central point of communication between Puma and investigators for all assigned clinical trial-related activities, to assure trials are conducted on time and budget while remaining fully compliant with ICH GCP and the SOPs in effect.

Major Duties/Responsibilities

- Conducts on-site visits consistent with the applicable Clinical Monitoring Plan and SOPs for site qualification, site initiation, interim monitoring, site close-out and other site visits (eg, booster)
- Writes confirmation letters, follow-up letters and site visit reports that conform with guidelines and timelines stated in the applicable Clinical Monitoring Plan and SOPs
- Facilitates preparation and collection of site level documents
- Assesses site performance and conducts training/re-training when necessary to ensure site compliance with the protocol, applicable regulations and Puma expectations
- Maintains communication with sites between visits to resolve issues (eg, data queries, study management), support the staff, oversee the efficient conduct of the trial, and ensure continued compliance
- Escalates site issues and collaborates with the study team and site staff to resolve issues
- Develops and maintains relationships with clinical site investigators and other site staff
- Assists site staff in maintaining audit/inspection readiness and in responding to any observations made by the auditor/inspector
- Performs additional activities as assigned:
  - Assists with budget negotiations under the direction of the Director/designee
  - Manages Clinical Operations vendors under the direction of the Director/designee
  - Represents Puma at key therapeutic meetings
  - Maintains operational expertise to support Clinical Science Liaison personnel
  - Conducts strategic negotiations with site staff
- 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 highly complex 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 site visits. 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
- Minimum of two years of health-related experience (eg, study coordinator, research lab, pharmaceutical/biotech company, CRO) or equivalent
- Strong understanding of GCP, ICH, and knowledge of regulatory requirements

Preferred:

- Oncology experience
- Global trial experience

Approvals

Employee

Signature_____ Date_____

Printed Name_____ Title_____

Supervisor

Signature_____ Date_____

Printed Name_____ Title_____