Job Description

Job title	Clinical Trial Manager
Department	Clinical Department
Employee Type	Full time, exempt
Working Location	San Diego, California, USA
Report to	Director, Clinical Operation

Summary

Ansun Biopharma, Inc. is a clinical stage biopharmaceutical company developing drugs for unmet medical needs. The individual will be primarily responsible for quality for clinical activities, including but not limited to conducting clinical monitoring, study site management and designed clinical activities efficiently and ensuring compliance with SOPs, GCPs and ICH guidelines. The Clinical Trial Manager (CTM) is responsible for the management of clinical trials from study start-up activities through the clinical study report. The CTM drives completion of all study deliverables, ensuring the highest level of data quality and compliance to quality standards and regulatory guidance; proactively identifies, communicates and resolves clinical study operational issues; and participates in process improvement initiatives as required.

Qualification / Education / Experiences / Skills

- **Education/Experiences**
  - Bachelor's degree or equivalent combination of education/experience in science or health-related field.
  - Minimum of 4 years of clinical trial management and 2+ years clinical research associate with on-site/remote clinical monitoring experience in the biotechnology/pharmaceutical/CRO industry
  - Global, registrational study experience.
  - Robust understanding of ICH/GCP, and knowledge of regulatory requirements.

- **Skills**
  - Strong clinical study/project management skills
  - Excellent communication, written and organizational skills (ability to prioritize a number of tasks of varying complexity), along with problem solving, conflict resolution, leadership and team-building skills.
  - Ability to motivate and collaborated with teams at other functional departments.
  - Ability to work independently, take initiative, and meet company goals within timelines and budget
  - Able to work in a fast-paced environment with multiple competing tasks and demands, across time-zones
  - Ability to communicate with vendors and keep a high quality of clinical study

- Strong knowledge of FDA regulations and willing to learn foreign regulatory requirements
- Proficient in Microsoft Office (excel, word, outlook, power point), electronic data capture (EDC) software (Medidata and others) and other platform related to electronic Trial Master File (eTMF) and safety report

Primary Responsibilities

- Manages all clinical aspects of study under oversight of Clinical Operations senior management including but not limited to initial operational feasibility, study timelines, budget and metrics; study document development and review (training documentation, ICF, study specific plans, eCRF Guidelines, lab and radiology manuals, etc.), plans and manages study-specific meetings (e.g. Study Team Meetings, Investigator meetings, etc.).
- Ensures clinical trials are executed in compliance with the protocol and ICH/GCP guidelines/regulations including but not limited to participate in the planning of quality assurance activities and coordinate resolution of audit findings; ensure audit-ready condition of clinical trial documentation; review monitoring reports to ensure quality and resolution of site-related issues.
- Execute clinical monitoring, site initiation visit and close out visits in adherence to Good Clinical Practices (GCPs) and ensure studies are in compliance with study protocol, appropriate Standard Operating Procedures (SOPs), and ICH/GCP regulations and study-specific manuals and procedures and write/revise the relevant reports, as necessary
- Work with QA for CAPA documentation and resolution.
- Manages the study submission to IRB/ECs in coordination with CRO, as appropriate.
- Assist selection activities for external vendors and is responsible for the management/oversight of external vendors including but not limited to the development vendor specifications; review vendor reports, budgets, and metrics;
- Provides study-specific training and delivers Sponsor's guidance to clinical research staff, including CRO, CRAs, sites and other contract personnel
- Conducts the internal review of investigator contracts and payments, as necessary.
- Prepares and presents project debriefings to Clinical Operations management.
- Uses operational and therapeutic expertise to optimize trial design and execution, and works with the study team to strategize on clinical trial execution.
- Works with the CRO and facilitate Sponsor clinical lead to select and approve sites and manages start-up processes toward activating sites; develops relationships with investigators and site staff.
- Interfaces with cross-functional teams (e.g. Medical Monitor, Regulatory Affairs, CMC/Supply Chain, CRO, vendors and Investigators/site staff). Works cross-functionally and with external vendors to proactively manage the execution of the clinical trial.
- Oversea TMF management and review TMF document as necessary
- Other duties as assigned