PALISADE BIO

Clinical Trials Assistant

POSITION SUMMARY

The individual in this job provides support to the clinical trial teams in areas which do not require knowledge of preclinical development, research design, and statistical methods. This is an entry level position for the clinical monitoring / study management development track. This position will report directly to the Sr. Clinical Trial Manager (CTM).

ROLE AND RESPONSIBILITIES

- Work to ensure timely review of regulatory documents for accuracy and completeness; communicate with investigator/study sites on document updates/corrections; liaise with monitors on trial documents and start-up activities, when needed; work with study team members to ensure approval of Informed Consent Forms/IRB approval; manage and track submissions of regulatory documents.
- With supervision, perform clinical study start-up activities consisting of managing the TMF, collecting and maintaining essential documents on clinical programs consisting of multiple studies running simultaneously.
- Prepare and organize site binders prior to site initiation visit.
- Identify vendors and best prices for ancillary study supplies.
- Assist with inventory, packaging and labeling of ancillary study supplies and expeditious handling resupply requests from sites
- Support the monitor team
- Serve as a resource to Clinical and other departments, when needed.
- Manage and ensure the timely submission, tracking and payment of clinical trial invoices.

QUALIFICATIONS AND EDUCATION REQUIREMENTS

- Bachelor's in medical, clinical, scientific, or related field from an accredited institution (or equivalent experience) preferred.
- Minimum 1 year of experience in clinical research, with previous clinical trial assistant, study coordinating or project management support at a sponsor or CRO.
- Knowledge of ICH/GCP and applicable regulations.

PREFERRED SKILLS

- Proficient in Microsoft software applications: Excel, Word, PowerPoint and Outlook.
- Able to take on moderately complex tasks with instruction and limited supervision.

- Able to maintain subject confidentiality and prevent inappropriate disclosure of confidential information to persons inside and outside of the organization.
- Excellent communication skills (oral/written).
- Pays careful attention to detail.
- Ensures that work outputs are highly accurate.
- Ability to work well with others.
- Good problem-solving skills such as identifying the key issues, assembling, and examining facts, and identifying several possible solutions.
- Strategic thinking capability and strong decision-making skills.