POSITION TITLE	**CLINICAL TRIAL MANAGER**
REPORTS TO	**CLINICAL TEAM**
MANAGES	**CLINICAL STUDIES**
LOCATION	**CHARLOTTE, NC AND MONTREAL, QUEBEC, CA**

DUTIES AND RESPONSIBILITIES

- Clinical Trial Manager supports study management in collaboration with Milestone's Clinical Team on multiple clinical studies. Duties include:
- Assists in start-up activities of clinical research studies including Investigator site selection;
- Assists in enrollment planning and conducting Investigator Meetings;
- Contributes to development of clinical protocols and study documents including: informed consent forms, study logs, study manuals, study plans, case report forms and guidelines;
- Assists in development of training materials and training of CRAs and other CRO personnel;
- Attends co-monitoring and/or training visits at clinical sites as required;
- Attends and co-monitor studies (PSV, SIV, IMV, COV) as needed;
- Manages investigational product accountability and reconciliation processes;
- Reviews site and patient-activity tracking data, prepare study updates and enrollment metrics and proactively identify and resolve study-related issues;
- Oversees performance of CROs, third-party vendors and CRAs to ensure compliance with study protocol and scope, identifying concerns and escalating to the Clinical Team;
- Reviews Monitoring Visit Reports from the CRO and escalates findings to the Clinical Team;
- Guides investigative site activities across multiple clinical trial sites, including but not limited to, SAE reporting, identification of protocol deviations, essential document status, eCRF completion, and investigational product accountability. Provide overall tactical support for Phase III studies;
- Ensures site compliance with GCP and federal and applicable local regulatory requirements;
- Leads or assist with TMF processes; set up, training, QC, management, archiving; and
- Develops and maintain excellent working relationships with investigators and study staff.

EDUCATION, BACKGROUND, KNOWLEDGE AND SKILLS

- Bachelor's degree or equivalent with a minimum of two-years' experience in clinical development and operations, including experience monitoring at clinical sites;
- Preferred experience is from a pharma sponsor or CRO; but will consider other experience;
- Must have thorough understanding of GCP and ICH regulations, clinical trial monitoring and regulatory compliance;
- Demonstrated effectiveness in resolving site management issues of varying complexity;
- Proficient in MS Excel, Word and PowerPoint. Knowledge of MS project preferred;
- Office-based position with travel averaging 25% ordinarily, and up to 75% during critical periods.

KEY ATTRIBUTES

- A resourceful, confident professional with strong communication and interpersonal/ team skills;
- Strong initiative and can-do attitude, with the ability to prioritize and multitask effectively; and
- Demonstrated ability to identify and resolve issues and effectively manage timelines.

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