JOB DESCRIPTION: SENIOR CLINICAL PROJECT MANAGER

Company: Vivet Therapeutics is committed to developing an innovative liver-directed gene therapy platform for the treatment of rare and severe inherited metabolic disorders

Job title: Senior Clinical Project Manager

Classification: Full-time position, based at Vivet Therapeutics Headquarters, Paris, France

Reports to: Head of Clinical Operations and Patient Advocacy Representative

Position summary: The Senior Clinical Project Manager (sCPM) is responsible for the management of all operational aspects of Clinical Trial Team activities for assigned project(s). The sCPM is accountable for achieving successful delivery – and reporting to upper management - of the clinical activities at the project level by meeting company and regulatory requirements according to time, quality/scope and budget constraints.

Essential Duties and Responsibilities: To perform this job successfully, an individual must be able to perform the following:

- Proactively manage project level operational aspects of Clinical Trial Team (CTT) including management of trial timeline, budget, resources and vendors.
- Provide regular and efficient updates on trial progress to upper management, with respect to vendor selection, project plans, trial budget, site selection, patient inclusion, timeline management, quality standards and risk mitigation.
- Ensure optimal relationship with sites/investigators/committees with the support of the CMO and/or the Head of Clinical Operations and Patient Advocacy Representative.
- Lead sponsor study startup process, including but not limited to conduct of the Trial Kick-off meeting, the set-up of trial master file (TMF), site selection and finalization of site and vendor Clinical Trial Agreements and budgets.
- Ensure effective management of the vendor in regard to patient's safety follow-up and the clinical trial(s) committees such as DMC or HAC with critical eye on organization and related documentation.
- Ensure effective project plans are in place and operational for each trial and work proactively with the Clinical Team to set priorities in accordance with applicable project plans, company standard operational procedures (SOPs), ICH/GCP guidelines and regulatory requirements.
- Ensure potential study risks are escalated to upper management when appropriate.
- Chair Clinical Team working group and vendor status update meetings and ensure meeting minutes are completed, distributed to team members and filed in the Trial Master File (TMF) in a timely manner.
- Review and approve site visit reports; ensure tracking, follow up and resolution of site issues have been completed in a timely manner.
- Monitor the quality of vendor deliverables, address quality issues with the appropriate team member and identify opportunities to improve training, execution and quality control across the clinical team.

- Ensure timely negotiation and implementation of vendor contracts within his/her responsibility in collaboration with the Legal representative.
- Review and approve vendor invoices in collaboration with the Accounting team to ensure investigator payments occur in a timely manner.
- Review and approve vendor responses to quality assurance audits for appropriateness, timeliness and accordance with company SOPs and regulatory requirements.
- Ensure all project level study documentation is filed in the TMF in accordance with company SOPs/all regulatory requirements and provide oversight to the clinical team regarding TMF filing, maintenance and archival procedures.
- Other duties as assigned.

Qualifications: To perform this job successfully, an individual must be able to perform each essential duty. The requirements listed below are representative of the knowledge, skill, and/or ability required.

Education/Experience: the ideal candidate will offer:

- Bachelor's degree in Life Sciences, Nursing Licensure or Pharmacy, at minimum
- Five or more years of clinical operations experience for CPM; with increasing levels of responsibility, in the Pharmaceutical, Biotechnology, Medical Device or CRO industry is required.
- Therapeutic experience in gene therapy and/or rare disease (preferred)
- Experience in early phase trials (Phase I-II) and First-In-Man trials (preferred)

Knowledge, Skills and Abilities:

- Quick takeover of the management of ongoing complex trial(s), flexibility, and team working.
- Read, write and speak fluent English; internationally minded, with excellent verbal and written communication skills.
- Hands-on with an eye for the details, while able to oversee and manage vendors appropriately.
- Must have a thorough knowledge of clinical research concepts, practices, EMA and FDA regulations and ICH Guidelines regarding drug development phases, clinical research and data management methods.

Work Environment: This is a high growth, fast paced small start-up biotech organization. The ability to be productive and successful in an intense work environment is critical. Willingness and ability to travel domestically and internationally is required, it is anticipated that this will be up to 20 % of work time.

The above job description is not intended to be an all-inclusive list of duties and standards of the position. Incumbents will follow any other instructions, and perform any other related duties, as assigned by their supervisor.