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Clinical Trial Manager

Bayside Solutions
Contract

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Bayside Solutions is seeking a highly motivated, **Clinical Trial Manager** to be a part of our partner's team in the South San Francisco Area. This is a unique opportunity to join a growing company dedicated to developing novel therapeutics to treat undertreated blood-based disorders.

The Clinical Trial Manager will work in close collaboration with the Clinical Operations & Regulatory Affairs leadership team. The CTM will be responsible for managing clinical trials, partnering with medical monitors and other internal and external parties to ensure clinical trial activities and deliverables are completed on time and within budget. The ideal candidate will have a BA/BS degree or higher, 3-5+ years' of clinical trial management experience, and be willing to travel up to 25%.

Our Company Bio: Bayside Solutions was founded in 2001, Bayside was recognized as one of the fastest growing professional staffing companies in Northern California. The numbers tell the story: We have close to a 100% client retention rate, 700% growth in four plus years and over 95% repeat business. Our dedication to building partnership relationships with both our clients and our recruits is the key to our phenomenal success.

You can find additional information on our company website at www.baysidesolutions.com.

Clinical Trial Manager:

Job Benefits:

- Work for a company that is local to the bay area and recognized as a leader of innovation.
- Competitive compensation commensurate with experience.
- This position is eligible for medical, vision, dental benefits, paid sick time, and 401K.

Summary of Responsibilities:

- Manage and lead the day-to-day operations of assigned studies to ensure completion per established project team goals and objectives in compliance with applicable GCP/ICH guidelines and other regulatory requirements.
- Manage and lead cross-functional study teams, including vendors; liaise with other functional areas (preclinical development, pharmaceutical sciences, safety, and regulatory affairs) in order to accurately coordinate clinical study activities.
- Coordinate clinical study timelines with Project management to meet critical milestones; escalate issues that may jeopardize timelines and deliverables.
- Conduct study monitoring visits and co-monitoring visits as needed.
- Provide regular updates of study progression to Clinical Development Lead, Program Management, and other stakeholders; proactively identify and resolve issues that arise during study conduct; manage escalation of study-related issues.

Company Info

Bayside Solutions

19 reviews

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- Lead development of study plans and system set-up; participate in preparation and ensure operational excellence of protocol, CRF, CSR and other key study team deliverables.
- Implement appropriate systems, standards and processes to ensure quality at the level of investigative sites, vendors and data; maintain clinical study files per ICH guidance.
- Lead preparation of vendor requirements and project scope and selection of study vendors; effectively manage interactions with vendor study team
- Lead feasibility assessment and selection of countries and sites for study conduct.
- Oversee the clinical aspects of timely data cleaning, data analysis and the availability of top line results; participate in data reviews and review of statistical analysis plans.
- Author, audit and/or edit written summaries of data reports, presentations, training material, and study documents (including pharmacy, laboratory, and operations manuals).
- Ensure set-up and implementation of effective investigator and site monitor training; coordinate operational and therapeutic area training for internal and external study team members.
- Provide oversight and direction to study team members, including vendors, for study deliverables.
- Coordinate with finance to track the financial status against budget.

Required Qualifications:

- BA/BS degree with at 3 - 5 years' of clinical trial management experience or advanced degree (MS/PhD/PharmD) with at least 2 years' clinical trial management experience.
- Ability to travel up to 25%.
- Strong experience in management of CROs and other vendors.
- Must have strong knowledge of ICH/GCP guidelines.
- Must have strong knowledge of protocol and clinical drug development. processes, clinical study design, study planning and management, and monitoring.
- Requires proven project management skills and study leadership ability.
- Must have excellent interpersonal, written and verbal communication skills, administrative skills and computer ability.
- Excellent computer skills in the following programs: MS Word, PowerPoint, Excel and Project.

Job Type: Contract

Required education:

- Bachelor's

Required experience:

- Clinical Trial Management: 3 years

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